Pest Management Regulatory Agency
Agence de réglementation de la lutte antiparasitaire

Regulatory Note

REG2004-02

Boscalid/BAS 510

The active ingredient boscalid (BAS 510) and associated end-use products, BAS 510 02F Crop Fungicide and BAS 510 02F Turf Fungicide, have been granted temporary registration under Section 17 of the Pest Control Products (PCP) Regulations for the control of Sclerotinia stem rot on canola; White mould on dried beans; Ascochyta blight, White mould and Gray mould on chickpeas and lentils; White mould and Gray mould on succulent beans; Lettuce drop (suppression) and Botrytis rot on lettuce (head and leaf); Early blight and Botrytis gray mould on the fruiting vegetable crop group (Crop Group 8, which includes eggplant, ground cherries, peppers [all varieties], tomatilo and tomato); Early blight on potato; Alternaria purple blotch and Botrytis leaf blight on the bulb vegetable crop group (Crop Group 3, which includes onions, dry bulb and green, garlic, leek and shallots); Alternaria leaf blight on carrots; Brown rot and Blossom blight on the stone fruit crop group (Crop Group 12, which includes apricots, cherry [sweet and tart], nectarine, peaches, plums, prunes and plumcotts); Botrytis gray mould on the small berry crop group (Crop Group 13, which includes blackberry, raspberry, currant, elderberry, blueberry [highbush only] gooseberry, huckleberry, loganberry); Powdery mildew on grapes; Botrytis gray mould on strawberries; as well as Dollar spot on golf course turfgrass.

This regulatory note provides a summary of data reviewed and the rationale for the proposed regulatory decision regarding these products.

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Foreword

Health Canada's Pest Management Regulatory Agency (PMRA) has issued temporary registration for boscalid (BAS 510) and the associated end-use product, BAS 02F Crop Fungicide and BAS 02F Turf Fungicide, for the control of Sclerotinia stem rot on canola; White mould on dried beans; Ascochyta blight, White mould and Gray mould on chickpeas and lentils; White mould and Gray mould on succulent beans; Lettuce drop and Botrytis rot on lettuce (head and leaf); Early blight and Botrytis gray mould on the fruiting vegetable crop group (Crop Group 8, which includes eggplant, ground cherries, peppers [all varieties], tomatilo and tomato); Early blight on potato; Alternaria purple blotch and Botrytis leaf blight on the bulb vegetable crop group (Crop Group 3, which includes onions, dry bulb and green, garlic, leek and shallots); Alternaria leaf blight on carrots; Brown rot and Blossom blight on the stone fruit crop group (Crop Group 12, which includes apricots, cherry [sweet and tart], nectarine, peaches, plums, prunes and plumcotts); Botrytis gray mould on the small berry crop group (Crop Group 13, which includes blackberry, raspberry, currant, elderberry, blueberry [highbush only] gooseberry, huckleberry, loganberry); Powdery mildew on grapes; Botrytis gray mould on strawberries; as well as Dollar spot on golf course turfgrass.

These products were reviewed jointly as reduced-risk products within the North American Free Trade Agreement's Technical Working Group on Pesticides (NAFTA TWG) Joint Review Program by Health Canada's PMRA and the United States Environmental Protection Agency (USEPA).

Methods for analysing boscalid (BAS 510) in environmental media are available to research and monitoring agencies upon request to the PMRA.

At the time these submissions were submitted, the registrant had not obtained certification for the final trivial name (boscalid) of this pesticide. Most of the information reviewed refers to the chemical code; BAS 510 or BAS 510 F.

BASF will be carrying out additional chemistry, toxicology, supervised residue trials, environmental chemistry and value studies as a condition of this temporary registration. Following the review of this information, the PMRA will publish a proposed registration decision document and request comments from interested parties before proceeding with a final regulatory decision.

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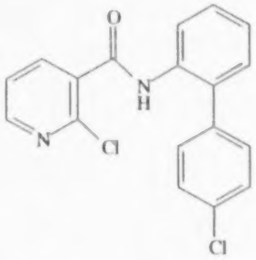
1.0 The active substance, its properties and uses

1.1 Identity of the active substance and impurities

Active substance	Boscalid (BAS 510 F, Nicobifen)
Function	Fungicide
Chemical name	
1. International Union of Pure and Applied Chemistry	2-chloro-*N*-(4′-chlorobiphenyl-2-yl)nicotinamide
2. Chemical Abstracts Service (CAS)	2-chloro-*N*-(4′-chlorobiphenyl-2-yl)3-pyridinecarboxamide
CAS number	188425-85-6
Molecular formula	$C_{18}H_{12}Cl_2N_2O$
Molecular weight	343.21
Structural formula	
Nominal purity of active	99% (limits 96.0%–100%)

Identity of relevant impurities of toxicological, environmental or other significance	The technical grade active ingredient boscalid contains Track 1 substances under the *Toxic Substances Management Policy* (TSMP). 1,2,3,4,6,7,8-heptachlorooxanthrene (HpCDD) was detected at 1.8 ppt in one out of five batches analyzed and octachlorooxanthrene (OCDD) was detected at 9.3 and 1.8 ppt, respectively, in two out of five batches. All other 2,3,7,8-substituted oxanthrenes were not detected in all five batches at the limit of quantitation (LOQ) of 4 ppt for 2,3,7,8-tetrachlorooxanthrene, 0.7 ppt for pentachlorooxanthrene, 1 ppt for total hexachlorooxanthrenes, 1.2 ppt for HpCDD and 2.4 ppt for OCDD.

1.2 Physical and chemical properties of active substances and end-use product(s)

Technical product: Boscalid Technical

Property	Result	Comment
Colour and physical state	White crystalline solid	
Odour	PAI: Odourless TGAI: Faint, smoky	
Melting point or range	142.8–143.8°C	
Boiling point or range	Not required for a solid	
Density	1.381 g/cm^3	
Vapour pressure at 20°C	7×10^{-7} Pa (by extrapolation from measurements made at 150 to 180°C)	Low vapour pressure
Henry's law constant at 20°C	$K = 9.73 \times 10^{-10}$ atm m^3/mol (5.17×10^{-8} kPa m^3/mol) $H = 4.05 \times 10^{-8}$ $1/H = 2.47 \times 10^{7}$	Not expected to be volatile from water and moist soil surfaces

Property	Result	Comment
Ultraviolet (UV)–visible spectrum	wavelength (nm) — ε 207 — 31 534 228 — 19 834 290 — 1529 300 — 531 Not expected to absorb at higher than 350 nm.	Not expected to phototransform in the environment
Solubility in water at 20°C	4.6 ± 0.06 mg/L	Low water solubility
Solubility (g/L) in organic solvents	Solvent — solubility g/L acetone — 160–200 acetonitrile — 40–50 dichloromethane — 200–250 NDF — >250 ethylacetate — 67–80 n-heptane — <10 methanol — 40–50 1-octanol — <10 olive oil — <10 2-propanol — <10 toluene — 20–25 NDF = N,N-dimethylformamide	Soluble in organic solvents
Octanol–water partition coefficient (K_{ow})	log K_{ow} = 2.96 ± 0.16	Borderline bioaccumulation potential
Dissociation constant (pK_a)	Not expected to dissociate.	
Stability (temperature, metal)	The product is stable at 54 ± 2°C for 14 days. It is a very weak reducing agent (reacts very weakly with potassium permanganate). It is not an oxidizing agent (does not react with iron, aluminum acetate, iron (II) acetate, water or the fire extinguishing agent monoammonium phosphate).	

End-use products: BAS 510 02 F Crop Fungicide
BAS 510 02 F Turf Fungicide

Property	Result
Colour	Light brown
Odour	N/A
Physical state	Solid granule
Formulation type	Water dispersible granule
Guarantee	70% (nominal) (limits 67.9%–72.1%)
Formulants	The product does not contain any USEPA List 1 formulants or formulants known to be TSMP Track 1 substances.
Container material and description	High density polyethylene
Bulk density	0.618 kg/L
pH of 1% dispersion in water	4.27 at 24.3°C
Oxidizing or reducing action	The product is a very weak reducer (reacts very weakly with potassium permanganate). It is not an oxidizer (does not react with iron, water or the fire extinguishing agent monoammonium phosphate.
Storage stability	No significant change of 24 months storage under warehouse conditions, in commercial packing.
Explodability	Not explosive

1.3 Details of uses

BAS 510 02F is a wettable granular formulation containing 70% boscalid (BAS 510). Boscalid (BAS 510) is a new active ingredient belonging to the anilide class of fungicides, which acts by inhibiting mitochondrial respiration and production of adenosine triphosphate (ATP) in fungal cells. Although it has systemic and curative properties, it is to be used as a protectant, that is, applied prior to spread of disease symptoms.

BAS 510 02F is proposed as two fungicide products: Crop Fungicide for foliar application to various crops including canola, pulses, bulb vegetables, carrots, fruiting vegetables, potatoes, lettuce, stone fruit, grapes, berries, strawberries and Turf Fungicide for foliar application to golf course turfgrass. It is accepted for control of selected diseases on these crops caused by the fungal pathogens *Alternaria, Ascochyta, Monilinia, Botrytis* and *Sclerotinia*.

2.0 Methods of analysis

2.1 Methods for analysis of the active substance as manufactured

Product	Analyte	Method type	Linearity range	Recovery (%)	RSD (%)	LOQ (%)	Method
Technical	Boscalid	HPLC-UV	8–24 mg/L	99.8	9.46	Not required	Accepted
Technical	Major impurities	HPLC-UV	0.8–40 mg/L	97.8–108.1	3.9–4.24	<0.05	Accepted

2.2 Method for formulation analysis

Product	Analyte	Method ID	Method type	Mean recovery (%) (n)	RSD (%)	Method
BAS 510 02	Boscalid	F-96	GC-FID	97.97 (9)	0.77	Accepted

2.3 Methods for environmental residue analysis

Pending review.

2.4 Methods for residue analysis

See Appendix III.

3.0 Impact on human and animal health

3.1 Integrated toxicological summary

A detailed review of the toxicological database available for the technical grade active ingredient (TGAI), BAS 510 F Technical and the formulations, BAS 510 02 F Crop Fungicide and BAS 510 02 F Turf Fungicide, has been completed. Data submitted were complete and comprehensive, and included the full battery of studies currently required for regulatory purposes. The studies were carried out in accordance with currently accepted international testing protocols and good laboratory practices (GLP). The scientific quality of the toxicology database is considered sufficient to adequately define the toxicity of this chemical for its intended purpose.

BAS 510 F was rapidly absorbed following oral administration with peak plasma concentrations (Cmax) being achieved within 8 hours following low (50 mg/kg bw) and high (500 mg/kg bw) dose administration. Following low dose administration approximately 56% of the administered dose was absorbed, this decreased to approximately 14–17% of the administered dose following high dose administration. No significant tissue accumulation was evident, less than 0.2% of the administered dose remained in the tissue/carcass at sacrifice (168 hours post-dosing). The major route of excretion was via the feces accounting for approximately 80–85% and greater than 90% of the administered dose following single low-dose and single or repeat high-dose administration, respectively. Urinary excretion accounted for approximately 15–17% and 3–5% of the administered dose following single low-dose administration and single or repeat high-dose administration, respectively. Within 48 hours, biliary excretion accounted for approximately 39–40% and 11–12% of the administered dose at the low and high dose, respectively. The majority was eliminated within 48 hours, greater than 85% at the low dose and greater than 90% at the high dose. BAS 510 F was rapidly and extensively metabolised. The metabolite characterization findings were consistent with Phase I oxidation followed by Phase II conjugation processes. The parent compound, BAS 510 F, was the predominant component identified in the feces. Major metabolites in the feces were identified as M510F01 and M510F06. In the urine, the major metabolites were identified as M510F01 and its glucuronic acid conjugate M510F02. Other metabolites identified in the urine included M510F48 and M510F05. Traces (less than 0.1%) of M510F47 (chloronicotinic acid) were identified following high dose administration. Traces (less than 0.11%) of the parent compound were detected in the urine following repeat high dose administration. In the bile, the major metabolites were identified as M510F02 and M510F05. Absorption, distribution and excretion did not appear to be significantly influenced by repeat high-dose oral administration, gender or position of the label. Slight gender differences were noted in the metabolite profile.

BAS 510 F Technical has low acute toxicity by the oral, dermal and inhalation routes of exposure; it was minimally irritating to the eyes and slightly irritating to the skin. The formulated products, BAS 510 02F Crop Fungicide and BAS 510 02F Turf Fungicide, have low acute toxicity by the oral, dermal and inhalation routes of exposure and are mildly irritating to the eyes and minimally irritating to the skin. Results of the dermal sensitization study for the technical grade active ingredient and the formulated products were negative; however, the dose levels for challenge treatment were not considered to be adequate for determination skin sensitization potential.

BAS 510 F was tested in a battery of in vitro (bacterial and mammalian cell gene mutation assays, mammalian cell chromosomal aberration assay and unscheduled DNA synthesis assay) and in vivo (mouse micronucleus assay) mutagenicity studies. There was no evidence of a genotoxicity potential in any of these assays; therefore, the weight of evidence suggests that BAS 510 F was not genotoxic under the conditions of the tests performed.

The subchronic and chronic toxicity of BAS 510 F was investigated in the mouse, rat and dog. A 4-week repeat dose dermal toxicity study was also carried out in rats. Treatment-related findings were noted in the liver in all species tested and in the thyroid in rats and dogs.

In mice, increased liver weights were noted in both sexes at 4000 ppm and above in the 90-day dietary study and in females at 2000 ppm and in both sexes at 8000 ppm in the 18-month dietary study. In the 90-day dietary study, the increased liver weights correlated with increased alanine aminotransferase (ALAT) activity in females and minimal to marked/severe fatty infiltration in the centrilobular hepatocytes in males. In the absence of any histopathological findings in the liver, the increased liver weights and alanine aminotransferase activity noted in females were considered to be an adaptive response to increased functional demand (metabolic). In the 18-month dietary study, the increased liver weights correlated with periportal hypertrophy in females at 2000 ppm and in both sexes at 8000 ppm and oval cell proliferation in females at 8000 ppm. In the 18-month dietary study, the increased liver weights and histopathological findings noted in the liver may be consistent with an adaptive response to increased functional demand (metabolic), however, the increased incidence of oval cell proliferation noted in females at 8000 ppm may be an indication of more severe damage since oval cells have been proposed to act as faculative stem cells within the liver. In the 18-month dietary study, lower body weight and body-weight gain were noted for males at 2000 ppm and in both sexes at 8000 ppm. In the 18-month dietary study, there was no evidence to indicate that BAS 510 F was oncogenic in the mouse. The NOAEL for the 90-day dietary study was 1000 ppm (197 mg/kg bw/d) for males and 8000 ppm (2209 mg/kg bw/d) for females. The NOAEL for the 18-month dietary study was 400 ppm (65 mg/kg bw/d) for males and 2000 ppm (443 mg/kg bw/d) for females.

In rats, increased serum γ-glutamyl transferase (GGT) activity and liver weights were noted for both sexes at 5000 ppm and above in the 90-day dietary study and in both sexes at 2500 ppm in the 2-year dietary study. The increased γ-glutamyl transferase activity and liver weights correlated with centrilobular hepatocellular hypertrophy in males at 5000 ppm and in both sexes at 15 000 ppm in the 90-day dietary study and in both sexes at 2500 ppm in the 2-year dietary study. Although these findings were considered to be treatment-related they were considered to be an adaptive response to increased functional demand (metabolic). Increased thyroid weights, diffuse follicular cell hypertrophy and focal follicular cell hyperplasia were noted in males at 2000 ppm and above and in females at 5000 ppm and above in the 90-day dietary study and in both sexes at 2500 ppm in the 2-year dietary study. Lower body weight and body-weight gain was noted in females at 2500 ppm in the 2-year dietary study. The NOAEL for the 90-day dietary study was 500 ppm (34 mg/kg bw/d) for males and 2000 ppm (159 mg/kg bw/d) for females. The NOAEL for the 2-year dietary study was 500 ppm (21.9 mg/kg bw/d) for both sexes.

Following 2-year dietary exposure, a treatment-related increased incidence of thyroid follicular cell adenomas was noted in male and female rats at 2500 ppm (110 and 150 mg/kg bw/d for males and females, respectively) with a higher incidence being noted in males than females. There was no treatment-related increased incidence of thyroid follicular cell carcinomas in either sex. In the rat, mechanistic studies indicate that BAS 510 F can cause increase liver weight with concomitant histopathological changes (proliferation/accumulation of smooth endoplasmic reticulum (SER) in the centrilobular hepatocytes and glycogen depletion in these hepatocytes) and induction of both phase I (oxidative) enzymes, as demonstrated by increased cytochrome P450 content, and phase II (conjugation) enzymes, as demonstrated by increased glucuronyl transferase activity. Mechanistic studies also indicate that BAS 510 F can cause increased thyroid weights with concomitant histopathology (diffuse follicular cell hypertrophy and focal follicular cell hyperplasia), decreased thyroid hormone (T3/T4) levels and increased thyroid-stimulating hormone (TSH) levels. Mechanistic data also indicate that these findings appear to be reversible upon cessation of treatment. Based on these findings, the thyroid tumours were most likely secondary to chronic induction of phase II microsomal enzymes in the liver. Induction of the hepatic microsomal phase II biotransformation system can increase the metabolism of thyroid hormones via conjugation resulting in increased clearance and decreased serum thyroid hormone levels (T3 and T4) that can trigger a compensatory increase in TSH levels. Chronic stimulation of the thyroid due to increased TSH levels is well known to result in thyroid follicular cell hypertrophy, hyperplasia and eventually neoplasia in rats. Published literature suggests that the rat is particularly sensitive to this secondary mechanism and that male rats are more sensitive than female rats. The data suggest that the mechanism of thyroid tumour development in rats following chronic dietary exposure to BAS 510 F was through a non-genotoxic mode of action; therefore, a non-linear margin of safety (MOS) approach to risk assessment for these tumours was considered to be appropriate for cancer risk assessment.

In dogs, increased alkaline phosphatase (ALP) activity, serum triglyceride levels and liver weights were noted in both sexes at 2500 ppm and above in the 90-day dietary study and in males at 2000 ppm and in both sexes at 20 000 ppm in the 1-year dietary study. Increased thyroid weights were noted in females at 25 000 ppm in the 90-day dietary study and in males at 2000 ppm and in both sexes at 20 000 ppm in the 1-year dietary study. No correlating histopathological findings were noted in either the liver or thyroid in the 90-day or 1-year dietary studies. The findings noted in the 1-year dietary study were consistent with findings noted in the 90-day dietary study at similar dose levels. The NOAEL for the 90-day dietary study was 250 ppm (7.6 and 8.1 mg/kg bw/d for males and females, respectively). The NOAEL for the 1-year dietary study was 800 ppm (21.8 and 22.1 mg/kg bw/d for males and females, respectively). The lower NOAEL noted in the 90-day dietary study when compared to the 1-year dietary study was considered to be due to the dose selection.

There was no evidence in the toxicology database to suggest a significant increase in toxicity with increased duration of exposure in mouse, rat or dog.

In a 4-week repeat-dose dermal toxicity study in the rat, there were no treatment-related systemic findings and no treatment-related signs of local dermal irritation at any dose level up to and including 1000 mg/kg bw/d, the highest dose tested. The NOAEL for systemic toxicity and local dermal irritation was 1000 mg/kg bw/d.

In the rat 2-generation reproduction (one generation per litter) study, reproductive function, reproductive parameters and litter parameters were not influenced by treatment in the F_0/F_1 generation at dose levels up to and including 10 000 ppm (1035 and 1062 mg/kg bw/d in males and females, respectively), the highest dose tested. In the parental animals, treatment-related findings were noted in F_0/F_1 males and females at 10 000 ppm and included lower body weight and body-weight gain (F_1 males), increased liver weights (F_0/F_1 females), minimal to moderate centrilobular hepatocellular hypertrophy (F_0/F_1 both sexes) and slight to marked/severe degeneration of centrilobular hepatocytes (F_0/F_1 males). In the absence of any other correlating findings in other liver function markers, the findings noted in F_0/F_1 females at 10 000 ppm were considered to be an adaptive response. In the offspring lower body weight and body-weight gain were noted in the F_1/F_2 pups at 10 000 ppm. The NOAEL for parental toxicity was 1000 ppm (101.2 mg/kg bw/d) for males and 10 000 ppm (1062 mg/kg bw/d) for females. The NOAEL for offspring toxicity was 1000 ppm (101.2 and 106.8 mg/kg bw/d in males and females, respectively). On the basis of the parental and offspring NOAELs neonates do not appear to be more sensitive than adults to exposure to BAS 510 F.

In the rat developmental toxicity study, there were no treatment-related maternal or developmental findings at dose levels up to and including 1000 mg/kg bw/d, the highest dose tested. The NOAEL for maternal and developmental toxicity was 1000 mg/kg bw/d. In the rabbit developmental toxicity study, dams at 1000 mg/kg bw/d exhibited lower body weight and body-weight gain. An increased incidence of abortions (2 on gestation day 27 and 1 on gestation day 29) and/or early delivery (1 on gestation day 29) were noted at 1000 mg/kg bw/d. Prior to aborting and/or premature delivery, the dams exhibited body-weight loss and lower food consumption that suggests that the increased incidence of abortions and/or premature delivery may be due to maternal toxicity. The NOAEL for maternal and developmental toxicity was 300 mg/kg bw/d. There was no evidence of any irreversible structural changes in either species; therefore, BAS 510 F was not considered to be teratogenic in rat or rabbit. On the basis of the maternal and developmental NOAEL's in the rat and rabbit developmental studies, no increased susceptibility of the fetus to in utero exposure to BAS 510 F was demonstrated in either species.

In the acute and subchronic neurotoxicity studies, there was no evidence to indicate that BAS 510 F was neurotoxic at the limit dose of 2000 mg/kg bw following acute exposure and at the limit dose of 1000 mg/kg bw/d following subchronic exposure. In a developmental neurotoxicity study, lower pup body weights were noted at 147 mg/kg bw/d and above; however, there was no evidence of developmental neurotoxicity at dose levels up to 1442 mg/kg bw/d, the highest dose tested. In the developmental neurotoxicity study, the maternal and offspring NOAELs were 1442 and 14 mg/kg bw/d, respectively. Based on this there was quantitative evidence to indicate increased sensitivity of the pups.

3.2 Toxicological endpoint for assessment of risk following long-term dietary exposure—ADI (OECD 2.3.2)

To account for the treatment-related lower pup body weight and body-weight gain noted in the rat developmental neurotoxicity study, in the absence of maternal toxicity, it is recommended that the rat developmental neurotoxicity study be used for determination of the acceptable daily intake. The recommended NOAEL is 14 mg/kg bw/d, based on lower pup body weight on post-natal day (PND) 4 and lower pup body-weight gain on PND 1–4 at the LOAEL (147 mg/kg bw/d, the next highest dose). It is recommended that the standard uncertainty factor (UF) of 100× be applied to account for intraspecies and interspecies variability. Although there was quantitative evidence to indicate increased sensitivity of the pups, no additional uncertainty factors are required since the recommended NOAEL was based on the findings noted in the pups.

The acceptable daily intake (ADI) proposed is calculated according to the following formula:

$$\text{ADI} = \frac{\text{NOAEL}}{\text{UF}} = \frac{14\ \text{mg/kg bw/d}}{100} = 0.14\ \text{mg/kg bw/day}$$

When the data were combined from the rat 2-year chronic toxicity and carcinogenicity studies, a treatment-related increased incidence of thyroid follicular cell adenomas was noted in both sexes at 2500 ppm (110 and 150 mg/kg bw/d for males and females, respectively). Chronic toxicity/carcinogenicity, genotoxicity and mechanistic data suggest that the mechanism of thyroid tumour development in rats following chronic dietary exposure to BAS 510 F was through a non-genotoxic mode of action (secondary to chronic induction of phase II microsomal enzymes in the liver); therefore, a non-linear MOS approach to risk assessment for these tumours was considered to be appropriate for cancer risk assessment. The NOAEL for the thyroid follicular cell adenomas is 500 ppm (21.9 and 30.0 mg/kg bw/d for males and females, respectively). The MOS for the thyroid follicular cell adenomas is 156.

The MOS for other critical endpoint(s) – calculated as NOAEL/ADI:

The most appropriate NOAEL for developmental toxicity is 300 mg/kg bw/d based on a slight increased incidence of abortions (2 on gestation day 27 and 1 on gestation day 29) and/or early delivery (1 on gestation day 29) at the LOAEL, 1000 mg/kg bw/d, in the rabbit developmental toxicity study. The MOS for developmental toxicity is 2142.

The most appropriate NOAEL for reproductive toxicity is 1035 mg/kg bw/d, the highest dose tested, based on the absence of any adverse treatment-related effects at this dose level in the rat 2-generation reproduction toxicity study. The MOS for reproductive toxicity is 7392.

3.3 Toxicological endpoint for assessment of risk following acute dietary exposure—ARfD (acute reference dose) (OECD 2.3.3)

An acute reference dose (ARfD) was not established since BAS 510 F was considered unlikely to present an acute hazard. There were no significant treatment-related findings in the acute, short-term, 2-generation reproduction or developmental toxicity studies to indicate a concern in acute dietary risk assessment.

3.4 Toxicological endpoint selection—occupational and bystander risk assessment

BAS 510 F Technical Fungicide has low acute toxicity by the oral, dermal and inhalation routes of exposure, it is minimally irritating to the eyes and slightly irritating to the skin. The formulated products, BAS 510 02F Crop Fungicide and BAS 510 02F Turf Fungicide, have low acute toxicity by the oral, dermal and inhalation routes, they are mildly irritating to the eyes and minimally irritating to the skin. Results of the dermal sensitization studies for the technical grade active ingredient and for the formulated products were negative, however, the dose levels for challenge treatment were not considered to be adequate for determination of skin sensitization potential.

BAS 510 F was rapidly absorbed with peak plasma concentration being achieved within 8 hours. Following low dose administration (50 mg/kg bw), approximately 56% of the administered dose was absorbed, absorption decreased to approximately 14–17% of the administered dose following high dose administration (500 mg/kg bw). No significant tissue accumulation was evident, less than 0.2% of the administered dose remained in the tissue/carcass at sacrifice (168 hours post-dosing). The major route of excretion was via the feces (greater than 80% of the administered dose) with the majority being eliminated within 48 hours (greater than 85% of the administered dose). The most prominent metabolites in the urine were identified as M510F01 (hydroxylation product) and its glucuronic acid derivative M510F02. In the bile, the major metabolites were identified as M510F02 and M510F05. In the feces, the parent compound, BAS 510 F, was the predominant component.

The subchronic and chronic toxicity of BAS 510 F was investigated in the mouse, rat and dog. In all species tested, treatment-related findings were noted in the liver. This was generally characterised by clinical chemistry findings, increased liver weights and centrilobular hepatocellular hypertrophy. In rats and dogs treatment-related findings were also noted in the thyroid. In dogs this was limited to increased thyroid weights in the absence of correlating histopathological findings. In rats, treatment-related findings in the thyroid were characterized by increased thyroid weights and diffuse hyperplasia and hypertrophy of the follicular epithelial cells following 90-day and 2-year dietary administration. Following 2-year dietary administration, a treatment-related increased incidence of thyroid follicular cell adenomas was noted in both sexes at 2500 ppm (approximately 110 and 150 mg/kg bw/d for males and females, respectively) with a higher incidence being noted in males than females. There was no treatment-related increased incidence of thyroid follicular cell carcinomas in either sex. Mechanistic data suggest that the treatment-related findings noted in the thyroid were most likely secondary to chronic induction of phase II microsomal enzymes in the liver leading to increased metabolism of thyroid hormones (T3 and T4) and a compensatory increase in TSH levels in an attempt to restore homeostatic conditions. In addition, mechanistic data also indicates that these findings appear to be reversible upon cessation of treatment. Chronic stimulation of the thyroid due to increased TSH levels is well known to result in follicular cell hypertrophy, hyperplasia and ultimately in neoplasia in rats with males being more sensitive than females. Additionally, BAS 510 F was not oncogenic in mice and there was no evidence that BAS 510 F was genotoxic. Based on data provided, a non-linear margin of exposure (MOE) approach to risk assessment for these tumours was considered to be appropriate. In mice, the NOAEL was 197 and 65 mg/kg bw/d following 90-day and 18-month dietary administration, respectively. In rats, the NOAEL was 34 and 21.9 mg/kg bw/d following 90-day and 2-year dietary administration, respectively. In dogs, the NOAEL was 7.6 and 21.8 mg/kg bw/d following 90-day and 1-year dietary administration, respectively (the lower NOAEL noted in the 90-day dietary study was considered to be due to dose selection and not a true indication of the NOAEL following 90-day dietary exposure).

There was no evidence in the toxicology database to suggest a significant increase in toxicity with increased duration of exposure in mouse, rat or dog.

A rat 28-day repeat dose dermal toxicity study was available; however, there were no adverse treatment-related systemic findings at dose levels up to 1000 mg/kg bw/d, the highest dose tested.

On the basis of the parental and offspring NOAELs in the rat 2-generation reproduction study, there was no evidence to indicate that neonates were more sensitive to exposure to BAS 510 F. Reproductive function, reproductive parameters and litter parameters were not influenced by treatment. The NOAEL for parental and offspring toxicity was 101 mg/kg bw/d. The NOAEL for reproductive toxicity was 1035 mg/kg bw/d. On the basis of the maternal and developmental NOAELs rat and rabbit developmental toxicity studies, there was no evidence to indicate an increased susceptibility of the fetus to in utero exposure to BAS 510 F in either species. In the rat, the NOAEL for parental and developmental toxicity was 1000 mg/kg bw/d. In the rabbit, the NOAEL for parental and developmental toxicity was 300 mg/kg bw/d. There was no evidence on either species to indicate that BAS 510 F was teratogenic.

In the acute and subchronic neurotoxicity studies, there was no evidence to indicate that BAS 510 F was neurotoxic at the limit doses of 2000 mg/kg bw following acute exposure and at 1000 mg/kg bw/d following subchronic exposure. In a developmental neurotoxicity study, lower pup body weights were noted at 147 mg/kg bw/d and above; however, there was no evidence of developmental neurotoxicity at dose levels up to 1442 mg/kg bw/d, the highest dose tested. In the developmental neurotoxicity study, the maternal and offspring NOAELs were 1442 and 14 mg/kg bw/d, respectively. Based on this there was quantitative evidence to indicate increased sensitivity of the pups.

To account for the treatment-related lower pup body weight noted in the rat developmental neurotoxicity study in the absence of maternal toxicity, it is recommended that the rat developmental neurotoxicity study be used for all proposed exposure scenarios. The recommended NOAEL is 14 mg/kg bw/d. Farmers, custom applicators, re-entry workers and bystanders (including adults and youth) have potential for short- to intermediate-term exposure to BAS 510 F via the dermal and inhalation routes. The body weight of 70 kg is considered the most appropriate for use in this assessment. When a developmental endpoint is chosen, often a body weight of 62 kg (median female body weight) is used in the assessment to be protective of the female working population. However, the exposure data is based on the surface area of a 70 kg person (median male and female body weight). Thus, using a female body weight with the exposure data would result in conservative (overestimated) exposure estimates. A margin of exposure (MOE) of 100 is recommended to account for intra- and inter-species difference. Although there was quantitative evidence to indicate increased sensitivity of the pups, no additional MOE is required since the recommended NOAEL was based on the findings noted in the pups.

An estimate of dermal absorption is required since an adequate endpoint from a dermal toxicity study was not available for use in the risk assessment. A dermal absorption value of 15% was selected based on a dermal penetration study submitted by the applicant. ^{14}C-BAS 510 F in distilled water was applied to the shaved dorsal surface (~ 10 cm^2) of male rats (four/group) at nominal doses of 0.01, 0.10, or 1.0 mg/cm^2 for periods of 1, 4, 10 or 24 hours. At the low dose two groups were washed at 10 hours and sacrificed at 24 and 72 hours. At the intermediate and high-dose, one group at each dose was washed at 10 hours and sacrificed at 72 hours. Fifteen percent dermal absorption was obtained in the 24 hour low dose group. This value incorporates skin-bound residues as the study data indicate that absorption from the skin bound residue continues after washing.

3.5 Impact on human and animal health arising from exposure to the active substance or to its impurities

3.5.1 Occupational exposure and risk

3.5.1.1 Handler exposure and risk

Farmers and custom applicators have potential for exposure to BAS 510 02F Crop Fungicide during application to bulb vegetables, fruiting vegetables, carrots, potatoes, beans (dry and succulent), chickpeas, lentils, canola, lettuce (head and leaf), berries, stone fruits, strawberries and grapes. Ground and aerial methods of application are proposed.

Typical areas treated per day range from 5 to 139 ha for farmers and up to 400 ha for custom applicators. Maximum rates of application range from 220 to 550 g a.i./ha. Farmers who were mixing/loading and applying BAS 510 02F Crop Fungicide would typically be exposed once every 7–21 days, 2 to 6 times during the growing season, which would result in short- to intermediate-term exposure intermittently throughout the growing season. Custom applicators may be exposed more frequently and the duration of exposure would be intermediate-term.

Golf course workers have potential for exposure to BAS 510 02F Turf Fungicide during mixing/loading and applying to golf course turf. Rates of application range from 224 to 280 g a.i./ha applied at a 14-day interval for no more than 2 sequential applications. The typical area treated per day ranges from 0.4 to 16 ha depending on the type of application equipment. Workers who were mixing/loading and applying BAS 510 02F Turf Fungicide would typically be exposed once every 14 days, 6 times during the growing season, which would result in intermittent short- to intermediate-term exposure.

Exposure estimates for mixers, loaders, applicators (M/L/A) are based on data from the Pesticide Handlers Exposure Database (PHED) and the studies by the Outdoor Residential Exposure Task Force (ORETF), of which BASF Canada is a member. PHED version 1.1 is a compilation of generic M/L/A passive dosimetry data with associated software which facilitates the generation of scenario-specific exposure estimates. With a few exceptions, the PHED estimates meet criteria for data quality, specificity and quantity outlined under the NAFTA TWG on Pesticides. To estimate exposure for each use scenario, appropriate subsets of A and B (and C grade for backpack inhalation) were created from the dry flowable mixer/loader; airblast, aerial and groundboom applicator; and backpack M/L/A database files of PHED. All data were normalized for kg of active ingredient handled. Exposure estimates are presented on the basis of the best-fit measure of central tendency, i.e., summing the measure of central tendency for each body part that is most appropriate to the distribution of data for that body part.

The ORETF generated several exposure studies which monitored exposure of lawn care technicians and homeowners mixing, loading and applying pest control products to turf and ornamentals. These studies are considered appropriate for use as surrogate data to estimate exposure during mixing, loading and applying BAS 510 02F Turf Fungicide to golf course turf, using hand-held equipment. Exposure was monitored using passive dosimetry, hand washes, face/neck wipes and personal air samplers. Exposure estimates are normalized for kg of active ingredient handled and presented on the median measure of central tendency.

The exposure estimates for BAS 510 02F Crop Fungicide are based on mixer/loaders wearing long pants, long-sleeved shirts and gloves and applicators wearing long pants and long-sleeved shirts. For BAS 510 02F Turf Fungicide, exposure estimates are based on long pants, long-sleeved shirts and gloves. Systemic exposure estimates were coupled with the NOAEL of 14 mg/kg/day from an oral toxicity study to obtain MOEs. All MOEs exceed the target of 100 and are considered acceptable. Results of the exposure and risk assessments are presented in Table 3.5.1.

Table 3.5.1 BAS 510 F Handler exposure estimates and margins of exposure

Scenario[a]	Equipment	Systemic Exposure[b] (mg/kg/day)	Margin of Exposure[c]
BAS 510 02F Crop Fungicide			
Farmer M/L/A	Ground boom	0.0009–0.019	750–15 960
Farmer M/L/A	Airblast	0.0070–0.017	810–2010
Custom M/L/A	Ground boom	0.022–0.045	310–630
Custom M/L	Aerial	0.044–0.079	180–320
Custom Applicator	Aerial	0.0026–0.0047	2990–5380
BAS 510 02F Turf Fungicide			
Golf Course M/L/A	Ground boom and handheld equipment	0.0014–0.0020	6960–9950

[a] M/L/A = mixer, loader, applicator. M/L = mixer, loader.

[b] Range of exposures are based on crop application rate, area treated per day and application equipment. Systemic exposure mg/kg/day = PHED unit exposure × application rate × area treated per day × conversion factor (mg/μg)/70 kg bw. A 15% dermal absorption value is incorporated into the systemic exposure assessment.

[c] MOE = NOAEL (mg/kg/day)/exposure (mg/kg/day). Based on a NOAEL of 14 mg/kg/day with a target of 100 from a DNT study.

3.5.1.2 Post-application exposure and risk

There is potential for post-application exposure to workers re-entering crops treated with BAS 510 02F Crop Fungicide to perform activities such as irrigating, thinning, scouting and hand harvesting crops. There is potential for post-application exposure to workers re-entering treated golf course turf to aerate, irrigate, scout and mow. The number of applications ranges from two to six on crops and up to six on turf. Half-lives range from 6 to 22 days and 0.6 to 2 days on crops and turf respectively. Thus, re-entry workers could be exposed to BAS 510 F residues intermittently throughout the growing season for an intermediate-term duration.

The primary route of exposure for re-entry workers is dermal through contact with foliar residues. Inhalation exposure is expected to be negligible as the vapour pressure of BAS 510 F is very low at 7×10^{-10} kPa at 20°C. Dermal exposure to workers re-entering treated areas is calculated by coupling crop specific dislodgeable foliar residue (DFR) or turf transferrable residue (TTR) values with activity specific transfer coefficients (TCs). Activity specific transfer coefficients are based on data generated by the Agricultural

Re-entry Task Force (ARTF), of which BASF Canada is a member. In addition, the applicant submitted four DFR studies and one TTR study to support the two end-use products.

Table 3.5.2 Summary of DFR and TTR Study Data

Study	Mean peak residue value $\mu g/cm^2$ ($n = 3$)	Half-life (days)	Rate per application (kg a.i./ha)	Total rate applied (kg a.i./ha/study)
Tomatoes, field	1.06	9	0.616	1.23
Grapes	1.42	could not determine	0.414	1.24
Peaches	1.3	15	0.258	1.29
Strawberries	1.83	6–22	0.414	2.07
Turf	0.131	0.6–2	0.39	1.17

For each study, the site with the highest peak residue was selected for use in the risk assessment. Four DFR studies were submitted; therefore, surrogate data was required for each remaining proposed crop. Surrogate data was determined using a weight-of-evidence approach. The study selection process compared the number of applications, rate per application, total rate applied, application interval, application equipment and ground crop versus orchard/trellis crop with the proposed use pattern.

Systemic exposure estimates, based on peak dislodgeable residues, were combined with the NOAEL of 14 mg/kg/day from an oral toxicity study to obtain MOEs. All MOEs are above the target of 100 with the exception of girdling table grapes. The MOE of 58 for girdling table grapes is considered to be acceptable due to the high-end DFR and dermal absorption inputs in the exposure algorithm resulting in a conservative (overestimated) assessment. All other MOEs exceeded the target MOE of 100 and are also considered to be acceptable.

Table 3.5.3 Re-entry exposure and risk estimates for BAS 510 F

Crop	Re-entry activity	Study	Exposure[a] mg/kg/day	MOE[b]
Beans, lentils, chickpea, canola	hand harvest, irrigate, scout, weed	Tomatoes, field	0.002–0.045	310–7700
Low Berries	hand harvest, prune, pinch, train, scout, weed, irrigate, thin, mulch	Strawberry	0.013–0.047	300–1120
Berries—vine/trellis	hand harvest, prune, train, tie, thin, scout, irrigate, weed, hedge	Peach	0.011–0.111	130–1260
Grapes	girdle	Grape	0.243	58
	train, tie, hand harvest, prune, thin, leaf pull, scout, irrigate, weed, hedge		0.012–0.122	115–1150
Stone Fruit	thin, hand harvest, prune, prop, train, tie, irrigate, scout, weed	Peach	0.022–0.067	210–630
Bulb Vegetables	hand harvest, thin, irrigate, scout, weed	Strawberry	0.009–0.078	180–1490
Potatoes	irrigate, scout, weed	Tomatoes, field	0.005–0.027	510–2570
Carrots	hand harvest, irrigate, scout, weed	Tomatoes, field	0.005–0.045	310–2570
Fruiting Vegetables	hand harvest, prune, stake, tie, thin, irrigate, scout, weed	Tomatoes, field	0.009–0.018	770–1540
Lettuce	hand harvest, irrigate, scout, weed	Tomatoes, field	0.009–0.045	310–1540
Golf Course Turf	aerate, fertilize, prune, scout, mow	Turf	0.010–0.015	910–1440

[a] Systemic exposure (mg/kg/day) = DFR or TTR (μg/cm^2) × TC (cm^2/h) × 8 h × 15% dermal absorption × conversion factor (mg/μg)/70 kg BW. DFR or TTR are based on the peak dislodgeable foliar or transferable residue value from the study.

[b] MOE = NOAEL/exposure, based on a NOAEL of 14 mg/kg/day with a target of 100 from the DNT study.

3.5.2 Residential exposure and risk

A residential exposure assessment was not required as the end-use products are not proposed for use in residential environments.

3.5.3 Bystander exposure and risk

There is limited potential for exposure to bystanders during application of BAS 510 02F Crop Fungicide and BAS 510 02F Turf fungicide with the exception of dermal exposure to adults and youths harvesting crops at pick-your-own operations and golfing. Adults and youth harvesting at pick-your-own operations have the potential for acute exposure to BAS 510 F residues as this activity is only expected to occur once per year. An acute reference dose was not selected for BAS 510 F as it is not considered to be acutely toxic, thus an exposure assessment was not required for the pick-your-own scenario. Exposure during golfing would be intermittent short- to intermediate-term in duration as there can be up to six applications per season with a half-life of 2 days. Exposure estimates were generated following the guidance in the USEPA *Draft Standard Operating Procedures (SOPs) for Residential Exposure Assessments.*

Dermal exposure estimates and margins of exposure (MOEs) were derived based on the NOAEL of 14 mg/kg/day. MOEs are above the target of 100 and are considered to be acceptable. Bystander exposure and risk estimates are presented in Table 3.5.4 below:

Table 3.5.4 Post-application exposure and MOEs for golfers

Population	Dermal exposure[a] mg/kg/d	Dermal MOE[b]
Adults	0.0006	24 880
Youth (10-12 years old)	0.001	13 860

[a] Dermal exposure = TTR (μg/cm^2) × TC (cm^2/h) × 4 h × 15% dermal absorption × conversion factor (mg/μg)/BW (70 kg for adults, 39 kg for youths). The TTR value is based on the mean peak values from the study.

[b] MOE = NOAEL/exposure, based on a NOAEL of 14 mg/kg/day with a target of 100.

An aggregate risk assessment is required as adults and youth have potential for exposure to BAS 510 F residues from both dietary (food and drinking water) and recreational sources via the oral and dermal routes. The aggregate risk assessment is presented in Section 4.2.

4.0 Residues

4.1 Residue summary

The nature of BAS 510 F residues in target (primary) crops is adequately described based upon ^{14}C metabolism studies conducted in grape, lettuce (head) and bean. No significant metabolism of BAS 510 F occurred in grapes or lettuce; unchanged parent was the only component identified, accounting for 92–98% and 99% TRR (total radioactive residues), respectively. In bean plants, BAS 510 F metabolized slowly; unchanged parent was the major component identified, accounting for up to 72% TRR in/on bean dry seeds and

99% TRR in/on bean plants; cleavage products 1-(chlorophenyl)-2-aminobenzene and 2-chloronicotinic acid were present in small amounts, accounting for <1% and <10% TRR, respectively. The parent BAS 510 F is the sole residue of concern for risk assessment and for enforcement for primary (target) crops.

The nature of BAS 510 F residues in rotational crops is adequately described, based upon a ^{14}C confined rotational crop study conducted with three representative crops (radish, head lettuce and wheat). In lettuce, radish (roots, tops) and wheat (forage), parent BAS 510 F was the major residue identified (50–96% TRR), with the glucoside metabolite, M510F61, accounting for 1–21% TRR; only parent was identified in wheat grain. The parent BAS 510 F is the sole residue of concern for risk assessment and for enforcement for rotational crops. Because quantifiable residues of BAS 510 F were observed in radish tops and roots and wheat forage, hay and straw at the longest (45-day) plantback interval studied, extensive rotational crop field trials are required (and have been submitted) to support the establishment of rotational residues/secondary residues maximum residue limits (MRLs) for rotational crop commodities.

The nature of BAS 510 F residues in livestock is adequately described, based upon ^{14}C metabolism studies conducted in lactating goat and laying hen. In both the goat and the hen, parent BAS 510 F, M510F01 (hydroxy metabolite) and M510F02 (M510F01 glucuronide) were identified as the major residues, with radioactivities ≥10% TRR. Based on the structural similarity of BAS 510 F and M510F01, and the fact that the enzymatic hydrolysis step in the proposed enforcement method (DFG S19) will release M510F02 back to free M510F01, the combined residues of parent BAS 510 F, M510F01 and M510F02 are the residues of concern for risk assessment and for enforcement in livestock matrices.

The data collection method (Method D9908) determines residues of BAS 510 F in plant matrices. Residues are extracted with an aqueous organic solvent mixture followed by liquid/liquid partitioning and column clean-up. The detection was achieved by the monitoring of ions m/z 343 to 307. Quantitation is by LC/MS/MS. The validated limit of quantitation (LOQ) is reported to be 0.05 ppm for residues of BAS 510 F in/on plant matrices.

The proposed enforcement method (Method D0008) determines residues of BAS 510 F in plant matrices. Residues are extracted using an aqueous organic solvent mixture followed by liquid/liquid partitioning and column clean-up. Quantitation is by GC/MS using selected ion monitoring (SIM). The method lists monitoring ions of m/z 342, 142, or 140, and notes that any ion can be used for quantitation. Adequate validation data were submitted, including independent laboratory validation (ILV) data. The validated LOQ is reported to be 0.05 ppm for residues of BAS 510 F in plant matrices.

The data collection method (Method 471/0) determines residues of BAS 510 F, M510F01 and M510F02 (as M510F01) in milk, eggs and animal tissues/organs. Residues are extracted with methanol. The extract is treated with a solution of β-glucuronidase and arylsulfatase to deconjugate M510F02 to M510F01. Residues are isolated by liquid/liquid partitioning followed by column chromatography. Parent BAS 510 F and total M510F01 are quantitated by LC/MS/MS. MS/MS detection was achieved by using the positive ionization mode monitoring ion transitions from m/z 359 to 140 and 323 for BAS 510 F and m/z 343 to 140 and 307 for M510F01. The reported LOQ for each analyte is 0.01 ppm in milk and eggs and 0.025 ppm in other animal matrices. Radiovalidation data are required. Contingent upon receipt of the radiovalidation data, this method is considered to be acceptable for collection of residue data for BAS 510 F and total M510F01 (free and deconjugated) in animal commodities.

A data collection method (Method 476/0) was developed to determine nonextractable residues of BAS 510 F in cow liver and milk. The method is a common moiety method based on the quantification of metabolite M510F53. Residues are mixed with ACN:concentrated acetic acid and extracted by microwave, followed by liquid-liquid partitioning and column clean-up. Quantitation is by GC/MS using selected ion monitoring. The MS detector uses SIM; ion *m/z* 167 was detected for M510F53. The reported LOQ is 0.01 ppm in milk and 0.05 ppm in liver. Contingent upon submission of radiovalidation data demonstrating the efficiency of the microwave hydrolysis step, this method is considered to be acceptable for purposes of collecting data on bound residues of BAS 510 F in cow liver and milk.

The proposed enforcement method (Method DFG S19) determines residues of BAS 510 F, M510F01 and M510F02 (as M510F01) in animal matrices. Residues are extracted with methanol. The extract is treated with a solution of β-glucuronidase and arylsulfatase to deconjugate M510F02 to free M510F01. Residues are isolated by liquid/liquid partitioning followed by column chromatography. Total M510F01 is acetylated followed by a column clean-up. Parent BAS 510 F and acetylated M510F01 are quantitated by GC/ECD (electron capture). Adequate validation data were submitted, including ILV data. The reported LOQ for each analyte is 0.01 ppm in milk and 0.025 ppm in other animal matrices. A radiovalidation study is required. Contingent upon submission of radiovalidation data, this method is considered to be acceptable for enforcement purposes in livestock matrices.

Residues of BAS 510 F and its metabolite M510F01 were not adequately recovered using the multiresidue methods. USEPA PAM protocol A was not applicable. USEPA PAM protocol B was not applicable for BAS 510 F and yielded inconsistent recoveries of M510F01. Residues of BAS 510 F and its hydroxy metabolite M510F01 had good responses with GC/ECD on a DB-1 column under USEPA PAM Protocol C. Neither analyte was recovered at ≥30% using Protocols D, E and F.

Submitted freezer storage stability data indicate that residues of BAS 510 F are stable in diverse representative crop matrices (sugar beet root, cabbage, canola seed, pea, peach and wheat grain, forage and straw) for up to approximately 1 year (ongoing study; further sampling planned at 18 and 24 months). These data support the freezer storage interval (from collection to analysis) of samples in the crop field trial, field accumulation and processing studies. Submission of the Final Report is required as a condition of the temporary registration; it should include a description of the fortification solutions (solvent) and a full description of the analytical method (445/0, LC/MS/MS).

BAS 510 F residues have been shown to be stable in peanut oil and meal stored frozen for up to 45 days (duration of study). These data support the freezer storage interval (from collection to analysis) of samples in the peanut processing study and other similar matrices. Freezer storage stability data are required for grape juice and tomato paste and tomato puree as a condition of registration.

Submitted freezer storage stability data for cattle and poultry matrices indicate that residues of BAS 510 F and its hydroxy metabolite M510F01 are stable for up to 5.5 months (duration of study) in cow milk, liver and muscle (only matrices tested) and 2.6 months (duration of study) in eggs (only poultry matrix tested). These data support the freezer storage interval (from collection to analysis) of samples in the cattle and poultry feeding studies.

Standard solutions (acetonitrile, solvent) of BAS 510 F and various metabolites (M510F01, M510F49, M510F51 and M510F53) were tested and found to remain stable during 62 days of storage (duration of study), either refrigerated in the dark or at room temperature with daylight exposure. The plant and livestock data collection and enforcement methods should each be revised to specify that standard solutions should not be stored longer than 60 days before replacement. The revised text is required as a condition of the temporary registration.

Supervised residue trials were conducted on the representative crops of the following crop subgroups/groups: Root Vegetables (except sugar beet), Tuberous and Corm Vegetables, Bulb Vegetables, Dried Shelled Pea and Bean (except Soybean), Fruiting Vegetables (Except Cucurbits), Cucurbit Vegetables, Stone Fruits, Berries, Tree Nuts, Pistachio, Cereal Grains, Grape, Peanut, Mint and Strawberry. Several of these trials were not conducted according to the proposed good agricultural practice (GAP) or in the required growing regions (as per Regulatory Directive DIR98-02); therefore, additional supervised residue trials will be required to support their uses. The commodities for which the uses were supported (including temporary registration) were: carrots, potato, Bulb Vegetables Crop Group 3, lettuce, the bean portion of Crop Group 6, Fruiting Vegetables Crop Group 8, the stone fruit Crop Group 12, the Berry Crop Group 13, canola and strawberries including all the imported crops: Tree Nut Crop Group 14, pistachios and peanuts. The temporary registration is conditional on the submission of additional supervised residue trials conducted at GAP in representative Canadian growing regions.

The processing studies, conducted on multiple matrices demonstrated that there was a slight concentration (1.31×) of residues of BAS 510 in canola oil. No significant concentration was observed in any other processed fraction.

Cattle and poultry feeding studies were conducted. Lactating dairy cows consumed BAS 510 F-laced feed for 29–30 days at levels equivalent to 1.8, 5.9 and 20.2 ppm in the diet. Laying hens were dosed daily for 29 days with encapsulated BAS 510 F at levels equivalent to 1.0, 5.3 and 19.6 ppm in the diet. Based on the residue data from the supervised residue studies and a calculation of maximum theoretical dietary burdens to determine a "worst case" diet, appropriate animal commodity MRLs (ranging from 0.02 to 0.35 ppm) are being proposed.

The BAS 510 chronic dietary exposure assessment was conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID™, Version 1.3) which incorporates consumption data from the USDA's Continuing Survey of Food Intakes by Individuals (CSFII), 1994–1996 and 1998. The 1994–96 and 1998 data are based on the reported consumption of more than 20 000 individuals over two non-consecutive survey days. Foods "as consumed" (e.g., apple pie) are linked to USEPA-defined food commodities (e.g., apples, peeled fruit: cooked; fresh or N/S; baked; or wheat flour: cooked; fresh or N/S, baked) using publicly available recipe translation files. Consumption data are averaged for the entire U.S. population and within population subgroups for chronic exposure assessment, but are retained as individual consumption events for acute exposure assessment. The assessment was carried out using proposed Canadian maximum residue limits (MRLs), on virtually all commodities. An EEC value of 1376 ppb was determined using the dug-out scenario (bulb vegetable application rate was used in the model). It was estimated that the chronic dietary exposure to BAS 510 from food and water represented approximately 51.9% of the ADI for children 1–2 years of age. The PDI for the remaining population subgroups, including infants, children, adults and seniors, each represented <45% of the ADI.

4.2 Residues relevant to consumer safety

Aggregate exposure and risk assessment

BAS 510 F is proposed for dietary and golf course turf uses. An aggregate risk assessment is required as adults and youths have potential for exposure to the active from both dietary (food and drinking water) and recreational sources via the oral and dermal routes.

Short- to intermediate-term exposure from golfing on treated turf was considered to co-occur with chronic oral exposure from food and drinking water. Acute dermal exposure from harvesting at pick-your-own facilities may also co-occur with acute dietary exposure; however, it was determined that an acute reference dose was not required for BAS 510 F as it is not acutely toxic. Thus, an acute aggregate exposure assessment is not necessary. Dermal and dietary oral exposure estimates were aggregated and coupled with the NOAEL of 14 mg/kg/day from the DNT study. All aggregate MOEs are above the target of 100. Thus, the aggregate risk assessment for adults and youth exposed to BAS 510 F through dietary and recreational uses is considered to be acceptable.

Table 4.2.1 Aggregate exposure and risk assessment

Scenario	Dietary exposure[a] mg/kg/d	Golfer exposure[b] mg/kg/day	Aggregate exposure[c] mg/kg/d	Aggregate MOE [d]
Adults	0.0396	0.0006	0.04	350
Youth	0.0413	0.001	0.042	330

[a] includes food and drinking water. See Section 4.1, dietary risk assessment for further details

[b] see Section 3.5 for further details

[c] where aggregate exposure (mg/kg/day) = $exp_{dietary} + exp_{bystander}$

[d] where aggregate MOE = NOAEL/aggregate exposure

5.0 Fate and behaviour in the environment

5.1 Physical and chemical properties relevant to the environment

BAS 510 F is of low water solubility (4.64 mg/L at 20°C) and is non-volatile ($<1 \times 10^{-6}$ Pa at 25°C); therefore, it is not expected to volatilize from moist soil surfaces or water (Henry's Law constant 9.73×10^{-10} atm·m^3·mol^{-1}). It does not dissociate in water and is not expected to undergo photolysis due to lack of absorbance greater than 300 nm. The log K_{ow} of 2.96 indicates some potential to bioaccumulate.

5.2 Abiotic transformation

BAS 510 F was stable in sterile aqueous solutions at pH 5, pH 7 and pH 9 at 25°C. Therefore, hydrolysis is not an important route of transformation for BAS 510 F.

BAS 510 F phototransformed slowly on soil under conditions of continuous irradiation with only 10% of the applied BAS 510 F transformed by the end of the 15-day study. The dark control showed no transformation during the study period. Therefore, soil photolysis is not an important route of transformation for BAS 510 F.

BAS 510 F phototransformed slowly in a sterile aqueous solution at pH 5 under continuous irradiation with only 6% of the applied BAS 510 F transformed by the end of the 15-day study. The dark control showed no transformation during the study period. Therefore, aqueous photolysis is not an important route of transformation for BAS 510 F.

5.3 Biotransformation

Aerobic soil: BAS 510 F concentration declined very slowly in aerobic soil. Most of the disappearance of the parent compound seems to be due to the formation of unextractable residues, which accounted for up to 60% of the applied radioactivity at study termination. The estimated DT_{50} values for BAS 510 F ranged from 138 to 578 days. The rate of decline appeared to be unrelated to microbial biomass, clay content, organic matter content, CEC or pH. The DT_{50} values greater than 371 days were extrapolated beyond the data and are of questionable value. M510F49 was identified as a major transformation product in only one soil (up to 14% applied radioactivity in Illinois silt loam). Significant mineralization was observed in only one soil (up to 25% applied radioactivity was $^{14}CO_2$ in German sandy loam). Volatile organics were not detected. BAS 510 F is classified as moderately persistent ($45 \geq DT_{50} < 185$ days) to persistent ($DT_{50} \geq 185$ days) in aerobic soil according to the classification of Goring et al. (1975).

Aerobic water/sediment systems: The transformation of BAS 510 F was investigated in two water/sediment systems (one pond system and one pond-like river side arm system). BAS 510 F rapidly partitioned to the sediments ("phase-transfer" DT_{50} values ranged from 3 to 9 days), where residues continued to increase until study termination (day 100). In the whole systems, the DT_{50} values for BAS 510 F were calculated to be 580–680 days (extrapolated). As with the soil studies, the disappearance of BAS 510 F is attributed to the binding of unextractable residues to sediment. No major transformation products were detected in the water layers or sediment extracts. BAS 510 F is classified as persistent ($DT_{50} > 185$ days) in aerobic aquatic systems according to the classification of McEwen and Stephenson (1979).

Anaerobic biotransformation: As in aerobic systems, BAS 510 F is persistent in anaerobic systems. In an anaerobic sediment/water system (pond), BAS 510 F rapidly partitioned to the sediment ("phase-transfer" DT_{50} ~4 days), where extractable residues declined very slowly (DT_{50} ~730 days in anaerobic sediment). Up to 55% of the applied radioactivity was sediment-bound. In the whole system, the DT_{50} was ~402 days. Major transformation products were not observed. The disappearance of BAS 510 F is attributed to the binding of unextractable residues to sediment.

5.4 Mobility

The adsorption of BAS 510 F depends on the type of soil, with adsorption increasing in proportion with organic matter content. Based on adsorption K_{oc} values ranging from 507 (sandy loam) to 1110 (sand/loamy sand), low mobility can be expected in most soils (McCall et al. 1981). Calculated desorption K_{oc} values ranged from 1243 (sandy loam) to 2977 (loam). The results also indicate that, in aquatic systems, BAS 510 F is expected to bind to sediment, which was observed in the aquatic biotransformation studies.

BAS 510 F is non-volatile and is not expected to volatilize from moist soil surfaces or water based on its vapour pressure ($<1 \times 10^{-6}$ Pa at 25°C) and Henry's Law constant (9.73×10^{-10} $atm \cdot m^3 \cdot mol^{-1}$). Volatilization of BAS 510 was not observed in the soil and aquatic biotransformation studies.

5.5 Dissipation and accumulation under field conditions

Canadian bareground plots: Generally, terrestrial field dissipation of BAS 510 F in Canadian soils was very slow and was mostly attributed to irreversible binding to the soil. Major transformation products were not detected at any of the sites (Ontario, Manitoba and Alberta), leaching of BAS 510 F was minimal (only detected in top 0–15 cm), and carryover of BAS 510 F was high (up to 96% of applied). In the Ontario soil, the dissipation of BAS 510 F was biphasic with DT_{50} values of 20 days for phase 1, and 365 days for phase 2. In this case, the more conservative estimate is the appropriate value for assessment purposes, as samples collected at the end of the study (day 360) still contained as much as 46% of the applied amount (mean was 20% of applied). The DT_{50} values for BAS 510 F were 585 days in the Manitoba soil, and 465 days in the Alberta soil. The total carryover of BAS 510 F (before freeze-up) was approximately 57%, 70% and 96% of the applied in the Ontario, Manitoba and Alberta plots, respectively. At the end of the study period (approximately day 360), the corresponding BAS 510 F residues were approximately 20%, 31% and 49% of applied. BAS 510 F is classified as persistent in soil ($DT_{50} \geq 185$ days) under Canadian field conditions according to the classification of Goring et al. (1975).

U.S. turf-cropped plots: Two U.S. field studies (New Jersey and Illinois) were conducted to compare dissipation of BAS 510 F in turf-cropped and bareground plots. BAS 510 F was less persistent in the turf-cropped plots. In Illinois, the DT_{50} values were determined to be 44 days (turf-cropped) and 108 days (bareground). In New Jersey, the DT_{50} values were determined to be 155 days (turf-cropped) and 244 days (bare ground). Leaching was minimal and the minor transformation products did not show a pattern of accumulation. No major transformation products were detected. At the end of the study period (day 344 or 359), the remaining BAS 510 F residues were 12–20% of the applied amount in any of the plots. BAS 510 F is classified as slightly persistent ($15 \leq DT_{50} < 45$ days) to moderately persistent ($45 \leq DT_{50} < 185$ days) in turf-cropped plots, according to the classification of Goring et al. (1975).

U.S. orchard-cropped plots: One U.S. field study (almond orchard in California) was conducted to compare dissipation of BAS 510 F in orchard-cropped and bareground plots. BAS 510 F was more persistent in the orchard-cropped plots. The DT_{50} values were determined to be >360 days (orchard-cropped) and 150 days (bareground). No transformation products were detected in any of the sites. BAS 510 F was primarily detected in the top 15 cm of the soil. At the end of the study period (360 days), the remaining BAS 510 F residues were 17–20% of the applied amount in both orchard-cropped and bareground plots. BAS 510 F is classified as persistent ($DT_{50} \geq 185$ days) in orchard-cropped plots according to the classification of Goring et al. (1975).

5.6 Bioaccumulation

The bioaccumulation of BAS 510 F in rainbow trout was studied at a nominal concentrations of 20 and 200 μg/L using 35-day exposure and 14-day depuration periods. The concentration of total radioactivity in fish tissues reached steady state within 3.3 days. Mean total [^{14}C]residues at steady state were highest in the inedible tissue compared to the edible and whole fish tissues. BAS 510 F was the major radioactive component recovered from the edible, inedible and whole fish tissues. The bioaccumulation factor (BCF) values for total [^{14}C]residues were 36–44×, 84–105× and 57–70× in edible, inedible and whole fish tissues, respectively. Depuration was rapid, with [^{14}C]residues accumulated in inedible tissues eliminated with a half-life of <1 day.

The bioconcentration of BAS 510 F in rainbow trout (BCF up to 105 in non-edible tissues) is in good agreement with the log K_{ow} value of 2.96, as a moderate level of bioconcentration was predicted. However, bioconcentration in benthic organisms such as clams and arthropod invertebrates was not evaluated and may be of importance in the field due to the rapid partitioning of BAS 510 F to the sediment and its long persistence.

5.7 Summary of fate and behaviour in the terrestrial environment

BAS 510 F is highly resistant to abiotic and biotic transformation. Some dissipation of BAS 510 F was observed in aerobic soils in the laboratory (DT_{50} 138–578 days), however the disappearance was attributed to the binding of unextractable residues to soil. Under field conditions in Canadian soils, BAS 510 F was persistent (DT_{50} 365–585 days). Based on U.S. field data, BAS 510 F can be expected to be less persistent in turf-cropped plots and more persistent in orchard-cropped plots. Carryover into the next growing season is expected to be significant (57–96% before freeze-up under Canadian conditions).

BAS 510 F is expected to have low mobility in soil, based on available adsorption/desorption data (K_{oc} 507–1110). The degree of soil binding was correlated with organic carbon content. The low tendency of BAS 510 F to leach was demonstrated in the field dissipation studies, where most of the material was found in the top 7.5 cm of soil.

5.8 Summary of fate and behaviour in the aquatic environment

BAS 510 F has low mobility in soil and low water solubility. However, BAS 510 F can enter aquatic environments through spray drift and surface runoff, where it is persistent. In water/sediment studies, BAS 510 F showed a bi-phasic phase transfer from water to sediment ("phase transfer" DT_{50} 3–9 days). The decline of BAS 510 F in whole aerobic or anaerobic aquatic systems (DT_{50} 402–680) is attributed to unextractable binding to sediment and is not attributed to transformation. Therefore, BAS 510 F is expected to accumulate in sediment.

5.9 Expected environmental concentrations

The cumulative application rates for turf uses are based on the maximum application rate (400 g a.i./ha), the maximum number of applications (6) and the minimum interval between application (14 days).

The cumulative application rates for crop uses are based on the maximum application rate for bulb vegetables (330 g a.i./ha), the maximum number of applications (6) and the minimum interval between each application (7 days).

5.9.1 Soil

The cumulative application rates were determined to be 2.3 and 2.0 kg a.i./ha for turf and crop uses, respectively, assuming 50% dissipation of BAS 510 F every 585 days (highest field DT_{50} in Canada). The resulting soil EEC values are 1.0 and 0.9 mg a.i./kg, for turf and crop uses, respectively, assuming BAS 510 F is evenly distributed in the top 15 cm of soil and the soil bulk density is 1.5 g/cm^3.

5.9.2 Aquatic systems

Aquatic habitat (pond): For a screening assessment, the cumulative application rates were determined to be 2.3 and 2.0 kg a.i./ha, for turf and crop uses, respectively, assuming 50% dissipation of BAS 510 F every 680 days (highest laboratory DT_{50} in whole aquatic systems). The resulting pond EEC values were 0.8 and 0.7 mg a.i./L, for turf and crop uses, respectively, assuming a direct overspray and water depth of 30 cm.

Drinking water: Drinking water concentrations of BAS 510 F in groundwater sources as a result of leaching were estimated over a 20-year period using the model LEACHM. Drinking water concentrations in surface water sources (reservoir and dugout) as a result of runoff were estimated using the model PRZM/EXAMS. Both surface water scenarios (reservoir and dugout) used data for soils that are highly susceptible to runoff and used weather data typical of a region where each are the primary source of drinking water.

Due to the conservative nature of the scenarios used for modelling, the EEC values in drinking water represent upper-bound estimates of potential pesticide exposure. The drinking water EEC values are summarized in Table 5.9.1. Water model input parameters are summarized in Appendix IV, Table 1.

Table 5.9.1 Estimated concentrations of BAS 510 F in drinking water sources

Crop	Ground water [μg a.i./L]		Reservoir concentration [μg a.i./L]		Dugout concentration [μg a.i./L]	
	Acute [1]	Chronic[2]	Acute[3]	Chronic[4]	Acute[3]	Chronic[4]
Turf	160	160	47.7	20.2	191	174
Vegetables	140	140	49.8	18	161	141

[1] 90th percentile of daily average concentrations

[2] 90th percentile of yearly average concentrations

[3] 90th percentile of yearly peaks

[4] 90th percentile of yearly averages.

5.9.3 Vegetation and other food sources

For a screening assessment, the cumulative application rates were determined to be 2.4 and 2.0 kg a.i./ha, for turf and crop uses, respectively, assuming no transformation occurs in wildlife food sources. The estimated EEC values of BAS 510 F in vegetation and insects are provided in Appendix IV, Table 2. Based on these values, the estimated EEC in the diet of non-target species immediately after application for representative non-target species are summarized in Table 5.9.2.

Table 5.9.2 Estimated concentrations of BAS 510 F in diets of terrestrial vertebrates

Organism	Diet	Dietary EEC in mg a.i./kg dw	
		Turf	Crops
Bobwhite quail	30% small insects 15% forage crops 55% grain	420	350
Mallard duck	30% large insects 70% grain	81	68
Rat	70% short grass 20% grain/seeds 10% large insects	1211	1009
Mouse	25% short grass 50% grain/seeds 25% leaves and leafy crops	1204	1003

6.0 Effects on non-target species

6.1 Effects on terrestrial organisms

BAS 510 F showed very low toxicity to earthworms in acute studies. No adverse effects were observed at the highest dose tested (1000 mg a.i./kg soil).

BAS 510 F was not toxic to worker honeybees after topical contact or oral uptake. The contact and oral LD_{50} values were determined to be >200 and >166 μg a.i./bee, respectively. Therefore, BAS 510 F is categorized as relatively non-toxic (LD_{50} >10.99 μg a.i./bee) to honeybees in accordance with Atkins et al. (1981) groups of relative toxicity. No sublethal effects were observed. Given that BAS 510 F is persistent, systemic (absorbed and translocated in plants), and applied throughout the growing season, chronic dietary exposure to honeybees cannot be ruled out. Therefore, a study is required to determine the concentrations of BAS 510 F in plant pollen/nectar.

No data were submitted on the effects of BAS 510 F on beneficial predatory and parasitic arthropods. Because exposure of these organisms is expected to occur, studies investigating the toxicity of a representative formulation of BAS 510 F to a parasitoid and a predatory mite species are required.

BAS 510 F was of low acute oral toxicity to birds since a single dose of 2000 mg a.i./kg bw by gavage did not induce any clinical signs or mortality in bobwhite quail. Therefore, BAS 510 F is categorized as practically non-toxic (LD_{50} >2000 mg a.i./kg bw) to birds on an acute oral basis in accordance with the USEPA descriptive categorization (USEPA 1985a). Similarly, it was of low short-term dietary toxicity because treatment for five consecutive days caused no treatment-related mortality in bobwhite quail or mallard duck. Therefore, BAS 510 F is categorized as practically non-toxic (LD_{50} >5000 mg a.i./kg diet) to birds on a short-term dietary basis in accordance with the USEPA descriptive categorization (USEPA 1985b). No sublethal effects were observed in the short-term dietary study with bobwhite quail; however, reduction of feed consumption was observed in mallard duck (NOEC 625 mg a.i./kg diet). In avian reproduction studies, no treatment-related effects were observed in mallard duck (NOEC 1000 mg a.i./kg diet); however, dietary administration to adult bobwhite quail reduced the number of eggs laid per hen and the number of 14-day old surviving chicks per hen (NOEC 300 mg a.i./kg diet).

The acute toxicity of BAS 510 F to mammals was low (rat LD_{50} >5000 mg a.i./kg bw). Clinical signs seen after oral exposure were fully reversible at non-lethal doses. In subchronic/chronic studies, the thyroid was the target organ. The lowest NOEC values for subchronic or chronic dietary exposure were 500 mg a.i./kg diet (90-day and 2-year rat studies) and 400 mg a.i./kg diet (18-month mouse). In a two-generation reproduction study in the rat, parental toxicity was observed in males from the F_0 and F_1 generations generally consisting of decreased body weight and body-weight gain and centrilobular hypertrophy (NOEC 1000 mg a.i./kg diet). The only effect seen in the offspring of the two-generation study was decreased body weight and body-weight gain (NOEC 1000 mg a.i./kg diet). In a developmental neurotoxicity study in the rat, no parental toxicity was observed; however, decreased body weight and body-weight gain was observed in the offspring (NOEC 100 mg a.i./kg diet).

For terrestrial plants, Tier I studies for vegetative vigour and seedling emergence were conducted at 611 g a.i./ha, which is equivalent to the maximum single application rate (612 g a.i./ha for control of *Botrytis* in field crops), but only 25% of the maximum cumulative application rate (2400 g a.i./ha). In both studies, the tomato was the most sensitive plant tested (22–24% reduction in shoot dry weight). Given that phytotoxic effects were observed, Tier II data are required to establish buffer zones for the protection of off-target terrestrial plants. The 611 g a.i./ha value was selected as an interim EC_{25} value for purpose of risk assessment and the determination of buffer zones for the protection of off-target terrestrial habitats.

6.2 Effects on aquatic organisms

Acute toxicity to freshwater organisms: BAS 510 F is moderately toxic to freshwater organisms in accordance with the USEPA descriptive classifications (USEPA 1985c,d). The 48-hour LC_{50} value was 5.3 mg a.i./L for *Daphnia magna* (NOEC 1.6 mg a.i./L). For the sediment-dwelling invertebrate, *Hyalella azteca*, the 10-day LC_{50} and NOEC (dry weight) values were >97 and 26 mg a.i./kg dw sediment. The 96-hour LC_{50} and NOEC (mortality and sublethal effects) values for rainbow trout were 2.7 and 1.9 mg a.i./L, respectively. No adverse effects were observed in bluegill sunfish or blue-green algae (*Anabaena flos-aquae*) at the highest dose tested (4.0 mg a.i./L), which was the maximum achievable test concentration limited by the solubility of BAS 510 F in water. The freshwater diatom (*Navicula pelliculosa*) and green alga (*Pseudokirchneriella subcapitata*) were more sensitive species of alga with corresponding 96-hour (biomass) EC_{50} values of 1.8 and 1.3 mg a.i./L and NOEC values of 0.14 and 0.49 mg a.i./L. The 7-day EC_{50} and NOEC values for frond necrosis of the vascular plant, *Lemna gibba*, were 1.8 and 0.5 mg a.i./L, respectively. The lowest NOEC of 0.14 mg a.i./L (freshwater diatom biomass) was selected for the purposes of risk assessment and determination of buffer zones for the protection of freshwater habitats.

Acute toxicity to estuarine/marine organisms: BAS 510 F is highly toxic to the Eastern oyster in accordance with the USEPA descriptive categorization (USEPA 1985e), whereas less than 50% mortality was observed at the maximum achievable test concentrations for mysid shrimp and fish. The 96-hour EC_{50} was 1.0 mg a.i./L for shell deposition of the Eastern oyster. Significant inhibition of shell deposition was observed at the lowest concentration tested (0.42 mg a.i./L); therefore, the NOEC was estimated to be 0.1 mg a.i./L based on 1/10 EC_{50}. For mysid shrimp, the 96-hour LC_{50} was >4.0 mg a.i./L. Approximately 10% mortality was observed at the lowest (0.4 mg a.i./L) and highest (4.0 mg a.i./L) test concentrations, indicating mortality was not dose-dependent. For the sheepshead minnow, the 96-hour LC_{50} and NOEC (mortality and sublethal effects) values were >4.0 and 2.3 mg a.i./L, respectively. The lowest (estimated) NOEC of 0.1 mg a.i./L

(1/10 EC_{50} for shell deposition of Eastern oyster) was selected for the purposes of risk assessment and determination of buffer zones for the protection of estuarine/marine habitats.

Chronic toxicity: Long-term exposure to BAS 510 F resulted in a reduction of young produced by *Daphnia magna* (21-day NOEC 1.3 mg a.i./L), and decreased emergence of the freshwater sediment-dwelling invertebrate, *Chironomus riparius* (28-day NOEC 2.0 mg a.i./L). The early life-stage study with rainbow trout indicates that chronic effects may occur at relatively low concentrations (97-day NOEC 0.12 mg a.i./L for lethargy and narcosis).

6.3 Effects on biological methods of sewage treatment

Data are not required.

6.4 Risk characterization

Risk assessment integrates the exposure and ecotoxicology data to estimate the potential for adverse ecological effects. The PMRA currently conducts a deterministic risk assessment of pest control products. Environmental risk is characterized using the margin of safety (MOS) method which is the ratio of the toxicity endpoint/EEC.

Risks are then classified based on the scheme presented in Table 6.4.1.

Table 6.4.1 Risk classification scheme

Margin of safety (MOS)	Degree of risk
≥10	Negligible
1 to <10	Low
0.1 to <1	Moderate
0.01 to <0.1	High
0.001 to <0.01	Very high
<0.001	Extremely high

6.4.1 Environmental behaviour

BAS 510 F is highly resistant to abiotic and biotic transformation. It does not hydrolyze or phototransform. Laboratory biotransformation studies resulted in DT_{50} values of 138–680 days in soil and water-sediment systems. Under field conditions in Canadian soils, BAS 510 F was persistent (DT_{50} 365–585 days), where disappearance is attributed to the binding of unextractable residues to soil. Carryover of BAS 510 F into the next growing season is expected to be significant (57–96% before freeze-up under Canadian conditions). As BAS 510 F is systemic (taken up and translocated in plants), chronic dietary exposure to terrestrial vertebrates and honeybees is possible. The concentrations of BAS 510 F in plant pollen/nectar is unknown, but have been requested. Adsorption studies indicate that soil binding increases with organic matter content. BAS 510 F has low mobility in soil and low solubility in water, but it is expected to leach over the long-term due to its persistence. BAS 510 F is also expected to enter aquatic systems through spray drift and surface runoff. It will partition to sediment and accumulate, as it does not transform.

6.4.2 Terrestrial organisms

Earthworms: For risk assessment, the lowest toxicity data from the studies available are used (NOEC 1000 mg a.i./kg soil). The cumulative soil EEC values for BAS 510 F are 1.0 and 0.9 mg a.i./kg soil, for turf and crop uses, respectively. The short-term MOS values (NOEC/EEC) are approximately 1000 for turf uses and 1110 for crop uses. The MOS values for earthworms indicate that the risk of lethal and sub-lethal effects of BAS 510 F to earthworms is negligible.

Honeybees: According to the classification by Atkins et al. (1981), BAS 510 F is classified as relatively non-toxic to honeybees (LD_{50} values were >200 and >166 μg a.i./bee for contact and oral exposures, respectively). Negligible risk of acute toxicity to honeybees is expected for products that fall into this category. Due to the persistence of BAS 510 F and its uptake by plants, chronic exposure can be expected to occur. A study is required to determine the concentrations of BAS 510 F in plant pollen/nectar for a honeybee chronic assessment.

Other beneficial arthropods: No data were submitted on the effects of BAS 510 F on beneficial predatory and parasitic arthropods. Because exposure of these organisms is expected to occur, studies investigating the toxicity of a representative formulation of BAS 510 F to a parasitoid and a predatory mite species are required.

Birds: The possibility that birds will be exposed to BAS 510 F (directly or indirectly) cannot be ruled out. Birds may be exposed to BAS 510 F mainly by the consumption of contaminated feed. The risk assessment procedure is directed at risks to individuals as there are currently no commonly used criteria for judging the significance of effects for population-level processes. The dietary EEC values for bobwhite quail were 420 and 350 mg a.i./kg diet, for turf and crop uses, respectively, while the corresponding dietary EEC values for mallard duck were 81 and 68 mg a.i./kg diet.

In the acute oral toxicity study with bobwhite quail, the mean body weight of individuals (BWI) in the control treatment was 0.21 kg/ind, and the mean food consumption (FC) was 0.02 kg dw diet/ind/day. The daily intake (DI = FC × EEC) was, therefore, 8.4 and 7.0 mg a.i./ind/day for turf and crop uses, respectively. The oral LD_{50} was >2000 mg a.i./kg bw. When expressed on a per individual basis, the $LD_{50(ind)}$ ($LD_{50} \times BWI$) was

>420 mg a.i./ind. Based on the DI and the $LD_{50(ind)}$, it would take a bobwhite quail greater than 50 and 60 continuous days of feeding, for turf and crop uses, respectively, to attain the dose equivalent to the LD_{50}. Therefore, BAS 510 F does not present an acute risk to the bobwhite quail at the proposed application rates.

The MOS values for short- and long-term dietary exposure assessments indicate that low to negligible risk to birds is expected (Table 6.4.2). Risk of adverse effects to bobwhite quail reproduction (reduction in surviving chicks per hen) is moderate as a result of long-term dietary exposure to the parent; whereas negligible risk to mallard duck reproduction is predicted.

Table 6.4.2 Avian risk assessment

Organism	Assessment	Endpoint (mg a.i./kg diet)	Margin of safety		Degree of risk
			Turf	Crops	
Bobwhite quail	Short-term dietary	LC_{50} >5000	>12	>15	negligible
		NOEC 5000	12	15	negligible
	Long-term dietary	NOEC 1000	2.4	2.9	low
	Reproduction	NOEC 300	0.71	0.86	moderate
Mallard duck	Short-term dietary	LC_{50} >5000	62	74	negligible
		NOEC 625	7.7	9.2	low
	Long-term dietary	NOEC 1000	12	15	negligible
	Reproduction	NOEC 1000	12	15	negligible

Small wild mammals: The possibility that mammals will be exposed to BAS 510 F (directly or indirectly) cannot be ruled out. Mammals may be exposed to BAS 510 F mainly by the consumption of contaminated feed. As with birds, the risk assessment procedure is directed at risks to individuals. The dietary EEC values for the rat were 1211 and 1009 mg a.i./kg diet for turf and crop uses, respectively, while the corresponding dietary EEC values for the mouse were 1204 and 1003 mg a.i./kg diet.

The food consumption (FC) for rats is 0.06 kg dw diet/ind/day, while the body weight of individuals (BWI) is 0.35 kg/ind. The daily intake (DI = FC × EEC) was, therefore, 73 and 61 mg a.i./ind/day for turf and crop uses, respectively. The reported LD_{50} value was >5000 mg a.i./kg bw. When expressed on a per individual basis, the $LD_{50(ind)}$ (LD_{50} × BWI) was 1750 mg a.i./ind. Based on the DI and the $LD_{50(ind)}$, it would take a rat greater than 24 and 29 continuous days of feeding, for turf and crop uses, respectively, to attain the dose equivalent to the LD_{50}. Therefore, BAS 510 F does not present an acute risk to the rat at the proposed application rates.

The MOS values for long-term dietary exposure assessments indicate that moderate risk of thyroid toxicity to small wild mammals is expected (Table 6.4.3). Risk of adverse effects on offspring (decreased body weight and body-weight gain in offspring) is high to moderate as a result of short-term dietary exposure to the maternal animals.

Table 6.4.3 Small wild mammal risk assessment (screening assessment)

Organism	Assessment	Endpoint (mg a.i./kg diet)	MOS		Degree of risk
			Turf	Crops	
Rat	Long-term dietary	NOEC 500	0.41	0.5	moderate
	Short-term dietary (offspring)	NOEC 100	0.1	0.1	high to moderate
Mouse	Long-term dietary	NOEC 400	0.33	0.4	moderate

Non-target plants: The EC_{25} of 611 g a.i./ha for the reduction of tomato shoot dry weight (interim value pending submission of Tier II data) was used to determine the risk of BAS 510 F toxicity to non-target plants. The maximum single application rates are 400 and 612 g a.i./ha, for turf and crop uses, respectively. The MOS values (EC_{25}/EEC) after a single application were calculated to be 1.5 for turf and 1.0 for crop uses. Therefore, plants are at low risk of adverse effects following a single direct overspray of formulated BAS 510 F.

The cumulative application rates were determined to be 2.3 and 2.0 kg a.i./ha, for turf and crop uses, respectively, assuming 50% dissipation of BAS 510F every 585 days (highest field DT_{50} in Canada). The MOS values (EC_{25}/EEC) were calculated to be 0.3 for turf uses and 0.3 for crop uses. Therefore, plants are at moderate risk of adverse effects (reduction in shoot weight) following cumulative exposure to a direct overspray.

6.4.3 Aquatic organisms

Although the proposed use does not include direct application to water, the possibility that aquatic organisms will be exposed to BAS 510F, directly or indirectly, cannot be ruled out. The cumulative pond EEC values for BAS 510F are 0.8 and 0.7 mg a.i./L, for turf and crop uses, respectively.

Acute toxicity to freshwater organisms: The most sensitive organism tested was the freshwater diatom, *Navicula pelliculosa* (NOEC 0.14 mg a.i./L for biomass). The results of the screening scenario (direct overspray) indicate that freshwater diatoms are at moderate risk of short-term toxicity (Table 6.4.5). Additional acute toxicity studies with a broader range of species indicate that two other freshwater species are also at risk (green algae and *Lemna gibba*).

Table 6.4.5 Acute freshwater risk assessment

Organism	Toxicity (mg a.i./L)	MOS		Degree of risk
		Turf	Crops	
Short-term risk to most sensitive species				
Freshwater diatom	NOEC 0.14	0.18	0.2	moderate
Short-term risk to other species				
Daphnia magna	NOEC 1.6	2	2.3	low
Rainbow trout	NOEC 1.9	2.4	2.7	low
Bluegill sunfish	NOEC 4.0	5	5.7	low
Blue-green alga	NOEC 4.0	5	5.7	low
Green alga	NOEC 0.49	0.61	0.7	moderate
Lemna gibba	NOEC 0.5	0.62	0.71	moderate

Acute toxicity to estuarine/marine organisms: The most sensitive organism tested was the Eastern oyster (1/10 EC_{50} 0.1 mg a.i./L for shell deposition). The results of the screening scenario (direct overspray) indicate that Eastern oysters are at moderate risk of short-term toxicity (Table 6.4.6). Additional acute toxicity studies with a broader range of species indicate that other estuarine/marine species are at low risk.

Table 6.4.6 Acute estuarine/marine risk assessment

Organism	Toxicity (mg a.i./L)	MOS		Degree of risk
		Turf	Crops	
Short-term risk to most sensitive species				
Eastern oyster	NOEC 0.1	0.12	0.14	moderate
Short-term risk to other species				
Mysid shrimp	NOEC 4.0	5	5.7	low
Sheepshead minnow	NOEC 2.3	2.9	3.3	low

Chronic toxicity: For a screening assessment, the MOS values for long-term exposure indicate that moderate risk of early life cycle toxicity (lethargy and narcosis) to fish is expected (Table 6.4.7). Risk of chronic effects on invertebrates is low.

Table 6.4.7 Chronic aquatic risk assessment

Organism	Toxicity (mg a.i./L)	MOS		Degree of risk
		Turf	Crops	
Daphnia magna	NOEC 1.3	1.6	1.9	low
Sediment-dwelling midge	NOEC 2.0	2.5	2.9	low
Rainbow trout	NOEC 0.14	0.18	0.2	moderate

6.5 Risk Mitigation

Based on available data, no restrictions of the application of BAS 510F are required for the protection of earthworms and honeybees.

Due to its persistence, BAS 510F has potential to enter aquatic systems and drinking water sources as a result of runoff and leaching. Therefore, the following label restrictions are required to minimize environmental exposure.

Under ENVIRONMENTAL HAZARDS:

- DO NOT apply to areas where runoff is likely to occur. Site characteristics that may lead to runoff following heavy rainfall include, but are not limited to: a moderate to steep slope, bare soil and poorly drained soils (e.g., soils that are compacted or fine textured). If rainfall is imminent, delay application.
- Boscalid is persistent and will carry over; it is recommended that the product, BAS 510 02F Crop Fungicide containing boscalid, not be used in areas treated with this product during the previous season.

A moderate risk of reproductive effects (reduced number of young per hen) was determined for birds. Moderate risk of thyroid toxicity to small wild mammals was predicted. Risk of adverse effects on small wild mammals (decreased body weight and body-weight gain in offspring) is high to moderate as a result of short-term dietary exposure to the maternal animal. A moderate risk of chronic effects on fish (lethargy and narcosis in the early life stage) was also predicted. Moderate risk of acute toxicity to non-target plants and aquatic organisms (freshwater and estuarine/marine) was predicted. Therefore, the following hazard statements and label restrictions are required.

Under ENVIRONMENTAL HAZARDS:

- Toxic to fish and other aquatic organisms, birds, mammals and off-target plants. Observe buffer zones specified under Directions for Use.

Under DIRECTIONS FOR USE:

- Do not apply during periods of dead calm or when winds are gusty. Do not overspray non-target terrestrial or aquatic habitats. Do not contaminate aquatic habitats when cleaning and rinsing spray equipment or containers.

On the BAS 510 02 F Crop Fungicide label under DIRECTIONS FOR USE:

- **Airblast application:** Do not direct spray above plants to be treated and turn off outward pointing nozzles at row ends and outer rows. Do not apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side.

- The buffer zones specified in the table below are required between the downwind point of direct application and the closest edge of sensitive terrestrial habitats (such as grasslands, forested areas, shelter belts, wood lots, hedgerows, pastures, rangelands and shrub lands), sensitive aquatic habitats (such as lakes, rivers, sloughs, ponds, coulees, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats.

Method of application	**Buffer zone (metres) required for the protection of:**		
	Freshwater habitat	**Estuarine/marine habitat**	**Terrestrial habitat**
Field sprayer	0	5	0
Airblast (early season)	5	15	5
Airblast (late season)	2	5	2
Aerial	0	5	5

On the BAS 510 02 F Turf Fungicide label under DIRECTIONS FOR USE:

- A buffer zone of 9 metres is required between the downwind point of direct application and the closest edge of estuarine/marine habitats. Self-contained bodies of water within the golf course property do not require buffer zones (e.g., ponds with no inflow or outflow of water).

7.0 Efficacy

7.1 Effectiveness

7.1.1 Intended uses

BAS 510 02F is a wettable granular formulation for spray application to foliage of various food crops and turf. The two products are proposed to control a range of diseases caused by *Alternaria, Ascochyta, Botrytis, Erysiphe, Leveillula, Sphaerotheca, Podosphaera, Uncinula, Monilinia, Rhizoctonia, Septoria* and *Sclerotinia.*

Specifically, BAS 510 02F Turf Fungicide is proposed for control of dollar spot on turf grass. BAS 510 02F Crop Fungicide is proposed for control of Sclerotinia stem rot and suppression of black spot on canola; control of white mould on dry beans; control of Ascochyta blight, white mould and gray mould on chickpeas and lentils; control of white mould and gray mould on succulent beans; control of lettuce drop, Botrytis rot and suppression of Rhizoctonia bottom drop on lettuce; control of early blight, Septoria leaf spot, powdery mildew and Botrytis gray mould on fruiting vegetables; control of early blight and white mould on potato; control of Alternaria purple blotch and Botrytis leaf blight on bulb vegetables; control of Alternaria leaf blight and powdery mildew on carrots; control of Alternaria leaf spot, powdery mildew, brown rot and blossom blight on stone fruit; control of Alternaria leaf spot, powdery mildew, Botrytis gray mould and mummy berry on (small) berries; control of powdery mildew and Botrytis gray mould on grape; and control of powdery mildew and Botrytis gray mould on strawberry. Details of accepted use directions are found in Table 7.6.1.

7.1.2 Mode of action

BAS 510 02F contains boscalid, an active ingredient which belongs to the anilide (carboxamide) class of fungicides. Boscalid inhibits the succinate-ubiquinone oxidoreductase system in Complex II of the mitochondrial electron transport chain, interfering with respiration and ATP production in fungal cells. This results in inhibition of spore germination, germ tube elongation, mycelial growth and sporulation. Activity is shown in vitro against *Alternaria, Botrytis, Monilinia* and *Sclerotinia.* Although the product has systemic and curative properties, it is to be used as a protectant, that is, first applied prior to spread of disease symptoms.

7.1.3 Crops

BAS 510 02F products are to be applied to canola, pulses, bulb vegetables, carrots, fruiting vegetables, potatoes, lettuce, stone fruit, grapes, small berries, strawberries and golf course turf grass.

7.1.4 Effectiveness against pests

7.1.4.1 BAS 510 02F Crop Fungicide

BAS 510 02F Crop Fungicide is proposed for control of various diseases caused by *Sclerotinia, Botrytis, Alternaria, Ascochyta, Rhizoctonia, Septoria, Monilinia* and powdery mildews on field crops, vegetable crops and fruit crops. Efficacy trials from field sites in Canada and the U.S. are included in this review.

Rationales were provided to extend the efficacy data on diseases caused by *Botrytis cinerea* and *Sclerotinia sclerotiorum* for certain crops to support claims for these pathogens to other crops. Based on the similar pathology of these species over a wide host range, this rationale was accepted in cases where it was possible to derive an appropriate application rate for the additional crops. A similar bridging approach was used for Alternaria early blight on tomatoes and potatoes. This extension could not be applied to other pathogen claims due to the more specific nature of the host/crop interaction of those pathogens or the need to derive a distinct product rate for each crop.

Aerial application was simulated in some efficacy trials on canola, dry bean and lentil by treatment at one of the proposed rates, using low water volume in the handheld boom sprayer. There was no significant difference in efficacy between BAS 510 applied at the same rate in low (40–50 L/ha) and in normal (100 L) water volumes by this method. Application by aerial sprayer will be required in supplementary trials to validate this approach.

Typically, efficacy results were not available for applications close to harvest which would determine the necessity of the proposed pre-harvest intervals. Same-day or 1-day PHIs are typical commercial practice for crops with sequential harvesting.

7.1.4.1.1 Canola

Sclerotinia stem rot *Sclerotinia sclerotiorum*	350–420 g/ha *250–290 g a.i./ha*
Black spot (suppression) *Alternaria brassicae*	350–420 g/ha *250–290 g a.i./ha*

Sixteen trials on Sclerotinia stem rot and one trial on black spot (suppression), mainly on Argentine canola, were provided from Manitoba, Saskatchewan and Alberta. Application rates of BAS 510 ranged from 100 to 500 g a.i./ha. Disease pressure was moderate to high in 9 trials for Sclerotinia stem rot. One application of BAS 510 at close to proposed label rates (250–300 g a.i./ha) provided control of Sclerotinia stem rot comparable to vinclozolin at 375 g a.i./ha (i.e., mean 58–70% control). There was no consistent trend related to rate of BAS 510, that is, increase in rate was not necessarily associated with significantly better disease control or higher yields. A lower rate of 200 g a.i./ha, however, was occasionally ineffective and thus the lowest consistently effective rate is 250 g. The upper rate was not justified and the statement that "use of a higher rate provides extended protection or increased yield" was not supported by data.

A single spray of BAS 510 02F was applied before 50% flowering (GS 61-65). A second application 1–2 weeks later was not tested in these trials; however, this is typical use pattern for other fungicides registered for this disease, when made at 50% flowering, not later.

Alternaria black spot was assessed in only one trial with low disease pressure. Additional studies on canola are required to confirm efficacy for this claim.

The data support the claim for control of Sclerotinia stem rot in canola at the lower proposed rate of 250 g a.i./ha. One application was supported but a second application 7–14 days later is also acceptable if this falls within the flowering period (i.e., should be revised to add 'up to 50% flowering'). Low water volume tests on canola suggest that aerial use would be acceptable, with confirmatory trials as a condition of temporary registration.

7.1.4.1.2 Dry beans (except for soybeans) group

White mould *Sclerotinia sclerotiorum*	560–770 g/ha *390–540 g a.i./ha*

Lupinus spp. (Includes grain lupin, sweet lupin, white lupin and white sweet lupin)
Phaseolus spp. (Includes field beans [dry common and coloured beans] such as kidney, black, cranberry, pink, navy bean, pinto bean, tepary bean and lima bean [dry])
Vigna spp. (Includes adzuki bean, blackeyed pea, catjang, cowpea, Crowder pea, moth bean, mung bean, rice bean, southern pea, urd bean)
Broad or fava bean (dry) [*Vicia* sp.]
Gaur [*Cyamopsis* sp.]
Lablab bean [*Lablab* sp.]

Seventeen trials on white mould of dry beans were provided from Manitoba, Alberta and Ontario. White, pinto, cranberry and red bean types were assessed. Application rates of BAS 510 ranged from 150 to 800 g a.i./ha. First applications were made at up to 4 different growth stages (GS 61-65, 10–40% flowering) and the PHI was at or greater than 21 days. Disease pressure was moderate or high in 8 trials.

Single applications at label rates provided moderate control (34–84%, $\bar{x} = 60$) of Sclerotinia white mould compared with 750 g/ha of vinclozolin (20–96%, $\bar{x} = 78$). In these trials, although an overall rate effect was not evident, the 500 g rate was typically more effective than 400 g and resulted in slightly higher yield at higher disease pressure.

In comparative trials, the two-application treatment of 300 g a.i./ha (less than proposed) was often more effective than a single spray of 400 g a.i./ha (67% vs. 58% control), suggesting that two sprays at label rate would be beneficial.

The data support the claim for control of white mould in dry beans at proposed rates of 390–540 g a.i./ha and the proposed timing of the two applications. The statement that use of a higher rate provides extended protection or increased yield was supported. Low water volume tests on bean suggest that aerial use would be acceptable, with confirmatory trials as a condition of temporary registration.

These data can be extended to cover white mould claims for most dry bean crops listed on the label, based on the fact that *Sclerotinia sclerotiorum* has a similar pathology over a wide host range and affects most of the crop genera proposed. Lablab and guar, however, are reported to be hosts of *Sclerotium rolfsii* rather than *Sclerotinia sclerotiorum*. Data on lettuce suggested that efficacy of BAS 510 02F is not consistent for different pathogens causing white mould and therefore the claim cannot be accepted on these two particular beans without confirmatory data.

7.1.4.1.3 Chickpeas and lentils

Ascochyta blight *Ascochyta* spp.	420 g/ha *290 g a.i./ha*
White mould *Sclerotinia sclerotiorum*	420 g/ha *290 g a.i./ha*
Gray mould *Botrytis cinerea*	420 g/ha *290 g a.i./ha*

Eleven trials on chickpeas (Desi and Kabuli types) and 8 on lentils from Manitoba, Alberta and Saskatchewan, all with BAS 510 02F, were reviewed. There were five trials for control of white mould, two for gray mould and the remainder were for control of ascochyta blight.

In Ascochyta blight trials, one application at close to the proposed label rate (300 g a.i.) of BAS 510 applied at GS 61-63 (10–30% flowering) was assessed. BAS 510 provided up to 89% ($\bar{x} = 60\%$) control of ascochyta blight in chickpeas (*Ascochyta rabiei*) under moderate to high disease pressure, at 4–5 weeks after treatment. In lentil trials, all treatments significantly reduced disease (*Ascochyta fabae* fsp. *lentis*) compared with the check, however the level of disease was generally too low to provide a valid contrast between treatments. This claim is supported by chickpea data, since Ascochyta is generally more difficult to control on chickpea than on lentil.

A second application after 7–14 days was not tested with BAS 510 02F in these trials. An optional second spray is typical use pattern for other fungicides registered for this disease, although it is timing of the first spray which is most critical.

In five Sclerotinia white mould trials, one application of BAS 510 was tested on both crops at rates from 100–600 g a.i./ha. Disease control with BAS 510 applied at approximately the proposed rate (300 g a.i./ha) was 40–75%, similar to vinclozolin performance, so this rate is accepted.

In two Botrytis gray mould trials on lentil, disease was significantly reduced by 53–72% with BAS 510 applied once at 300 g a.i./ha. These data are supplemented by one trial on succulent beans at the same rate.

The data support the claim for control of ascochyta blight and white mould of chickpea and lentils with one application of BAS 510 02F at the proposed rate of 290 g a.i./ha. The second application for ascochyta is also acceptable based on typical use pattern for fungicides for this disease. Limited data on gray mould on lentil can be combined with one trial on succulent bean to support this claim on the three crops at the rate proposed for pulses (290 g a.i./ha). Low water volume tests on lentil suggest that aerial use would be acceptable, with confirmatory trials as a condition of temporary registration.

7.1.4.1.4 Succulent beans group

White mould *Sclerotinia sclerotiorum*	560–770 g/ha *390–540 g a.i./ha*
Gray mould *Botrytis cinerea*	560–770 g/ha *390–540 g a.i./ha*

Phaseolus spp. (Includes runner bean, snap bean, wax bean, lima bean [green], broad bean [succulent])
Vigna spp. (Includes asparagus bean, Chinese longbean, podded bean, blackeyed pea, moth bean, yardlong bean, southern pea)
Canavalia spp. Jack bean

Six trials were reviewed on snap beans from Oregon, Michigan, California and Ontario for white mould control and one trial from British Columbia for control of Botrytis gray mould. Application rates of BAS 510 ranged from 150–800 g a.i./ha for single applications and 280–560 g for two applications. First applications were made at 4 different growth stages (GS 61-63, 10–40% bloom) and second applications were made up to 50% bloom (GS 65). Disease pressure was moderate to high in four trials.

Applications at close to proposed rate (400–560 g a.i./ha) of BAS 510 in all trials provided 50–82% ($\bar{x} = 69$) control of white mould, comparable to that provided by iprodione and benomyl (1 trial) but less than vinclozolin ($\bar{x} = 82$). In comparative trials, the 560 g a.i./ha rate of BAS 510 was more effective than 400 g rate but there were insufficient data points to determine a lowest effective rate. The split application was also effective but there are insufficient trials to confirm any benefit over single applications. However this is consistent with the use pattern of other fungicides registered for this disease and therefore two applications at proposed rates is acceptable. The statement that use of a higher rate provides extended protection or increased yield was not supported by the data.

In one trial, gray mould was significantly reduced by 50–73% with both 300 and 400 g a.i./ha applications of BAS 510, comparable to vinclozolin. Based on similar pathology of *Botrytis cinerea* on legume crops, this data can be combined with data on lentils to support a rate of 290 g a.i./ha for gray mould control. There were insufficient trials to justify the higher rate proposed for this disease (390–540 g a.i./ha) on succulent beans.

The data support a claim for control of white mould on succulent beans at the rate of 390–540 g a.i./ha and 1–2 applications as proposed. Limited data on gray mould can be combined with trials on lentils to support this claim on lentils, chickpeas and succulent beans, however this is based on a reduced rate of 290 g a.i./ha.

Supported claims on snap beans may be extended to include these diseases on other listed succulent bean types as proposed.

7.1.4.1.5 Head and leaf lettuce

Lettuce drop *Sclerotinia minor, Sclerotinia sclerotiorum*	385–770 g/ha *270–540 g a.i./ha*
Botrytis rot *Botrytis cinerea*	385–770 g/ha *270–540 g a.i./ha*
Rhizoctonia bottom rot (suppression) *Rhizoctonia solani*	385–770 g/ha *270–540 g a.i./ha*

Reports of 14 trials on lettuce were submitted from various U.S. sites. All treatments were applied preventatively, typically as single products, with 2–5 applications and intervals of 1–3 weeks between sprays. Yield was not assessed.

Ten trials on control of lettuce drop (*Sclerotinia sclerotiorum, Sclerotinia minor*) were submitted from California, Arizona and New York. In two of three trial sites where both pathogens were assessed, *Sclerotinia sclerotiorum* was more prevalent and less effectively controlled than *Sclerotinia minor*. In the five trials with *Sclerotinia minor*, BAS 510 applied at 200–560 g a.i./ha provided moderate control averaging 50%, similar to iprodione and vinclozolin. In four trials with *Sclerotinia sclerotiorum*, disease control with BAS 510 was 30% on average and consistently lower than vinclozolin. None of the products gave a high level of control and BAS 510 effect was equivalent to commercial standards for *Sclerotinia minor*, therefore the label claim for lettuce drop is acceptable for *suppression* of disease due to *Sclerotinia minor* only.

Three trial reports (California and Mississippi) were submitted on control of Botrytis rot in inoculated lettuce. BAS 510 applied at 157–302 g a.i./ha every 7–10 days provided significant reduction in disease incidence, typically 68–81% control, similar to commercial standards. In two of three comparative trials there was no apparent rate effect so that a rate of 200 g a.i./ha would likely be sufficient for Botrytis alone. In practice, the need for Sclerotinia control will determine the application rate of BAS 510 for lettuce.

One trial from Mississippi showed that BAS 510 at 235–305 g a.i./ha provided 35% reduction (suppression) of Rhizoctonia bottom rot when found together with Sclerotinia symptoms. There are no data for this pathogen on any other crops, therefore additional trials on lettuce are required to support an efficacy claim.

The data support claims for control of Botrytis rot and *suppression* of *Sclerotinia minor* on lettuce with BAS 510 applied at the lower proposed rate of 270 g a.i./ha and two applications. There were insufficient data to determine a lowest effective rate for *Sclerotinia*, however the higher proposed rate of 540 g a.i./ha rate did not appear to be justified and should be deleted. A reduced rate of 200 g a.i./ha is sufficient for Botrytis alone.

7.1.4.1.6 Fruiting vegetables (except cucurbits) group

Early blight *Alternaria solani*	175–315 g/ha *120–220 g a.i./ha*
Septoria leaf spot *Septoria lycopersici*	175–315 g/ha *120–220 g a.i./ha*
Powdery mildew *Leveillula taurica*	175–315 g/ha *120–220 g a.i./ha*
Botrytis gray mould *Botrytis cinerea*	630–875 g/ha *440–610 g a.i./ha*

A total of 21 reports were provided, of which 13 were from North American sites with adequate disease pressure. All of these trials were on field tomato. All treatments were applied preventatively, on a 7–14 day schedule, with 2–13 applications. In addition to foliar disease, fruit rot, marketable yield and total yield were assessed in some of the trials.

Early blight was assessed in 11 trials from Ontario, Michigan, Pennsylvania, North Carolina, Tennessee and Florida. In most trials with moderate to high disease pressure, BAS 510 applied at 100–240 g a.i./ha provided excellent control ($\bar{x} = 77\%$) by reducing either disease incidence or severity. In comparative trials, the lowest proposed rate (100–120 g) was as effective as a higher rates (168–240 g) and at least as good as standards such as azoxystrobin or chlorothalonil, although not as effective as pyraclostrobin. In some trials, however, yield data collected at 7–28 days after treatment showed a numerical increase with higher rates of BAS 510, which can therefore support the higher proposed rate.

Septoria leaf spot was assessed in two trials from North Carolina. BAS 510 applied at 112 or 224 g a.i./ha and a 7-day interval showed good efficacy in both trials, although numerically less effective than the strobilurins. These data suggest that BAS 510 is likely to provide good control of Septoria leaf spot; however, there are no data for this disease on any other crops and a minimum of three trials on field tomato was not met. Therefore additional trials on field tomato are required to confirm efficacy and to clarify if the higher rate is needed.

No data were submitted to support a claim for Botrytis gray mould. Based on similar pathology of Botrytis and similar crop canopy structure, data on succulent beans and pulses can be used to support this claim on field tomato, however with these data only a rate of 290 g a.i./ha is supported.

No data from Canada or the U.S. were submitted to support a claim for powdery mildew (*Leveillula taurica*) on field tomato and based on insufficient support for this disease on other crops, additional data on tomato are required.

The data support a claim for control of early blight on field tomato, at 120–220 g a.i./ha as proposed. Based on legume data, a claim for control of Botrytis gray mould is supported at a reduced rate of 290 g a.i./ha.

Supported claims based on data for field tomato i.e., early blight and Botrytis gray mould, are extended to include these diseases on other listed fruiting vegetables (Solanaceae).

7.1.4.1.7 Potato

Early blight *Alternaria solani*	175–315 g/ha *120–220 g a.i./ha*
White mould *Sclerotinia sclerotiorum*	560–700 g/ha *390–490 g a.i./ha*

No data from Canada or the U.S. were submitted to support a claim for early blight (*Alternaria solani*) on potato. Based on similar epidemiology of early blight and similar crop structure, however, data on field tomato can be extended to support a similar rate of BAS 510 (120–220 g a.i./ha) for this disease on potato. The other use directions should remain as proposed for potato.

Two trials from Oregon and Washington were submitted to support a claim for white mould on potato. Disease pressure was low and BAS 510 applied at 450–500 g a.i./ha provided only moderate control. The ambivalent results in two trials on potato suggest that substantial additional data on this crop are required.

Based on similar epidemiology and crop structure, data on early blight of tomato can be extended to support the proposed rate of 120–220 g a.i./ha for this disease on potato.

7.1.4.1.8 Bulb vegetables

Alternaria purple blotch *Alternaria porri*	475 g/ha *330 g a.i./ha*
Botrytis leaf blight *Botrytis squamosa*	475 g/ha *330 g a.i./ha*

A total of 24 reports were provided on diseases of onion caused by *Alternaria porri* and *Botrytis squamosa*, of which 7 from northern states (Oregon, Michigan, New York) and 4 from southern states (Texas, California) were acceptable for review.

Among six Alternaria purple blotch trials, BAS 510 applied alone at 224 or 336 g a.i./ha provided good control of purple blotch under low to moderate disease pressure. Performance of BAS 510 was similar to vinclozolin or iprodione. There were insufficient comparative trials to determine if 224 g a.i./ha was the lowest effective rate and the proposed rate of 330 g a.i./ha is accepted pending further data.

In three Botrytis leaf blight trials, BAS 510 applied alone at 224 or 336 g a.i./ha provided moderate control of leaf blight under moderate disease pressure. There were insufficient comparative trials to determine if 224 g is the lowest effective rate and the proposed rate of 330 g a.i./ha is accepted pending further data.

The data on onion support a claim for control of Alternaria purple blotch and Botrytis leaf blight on bulb vegetables.

Supported claims on onion may be extended to include these diseases on other bulb vegetables.

7.1.4.1.9 Carrots

Alternaria leaf blight *Alternaria dauci*	315 g/ha *220 g a.i./ha*
Powdery mildew *Erysiphe* spp.	315 g/ha *220 g a.i./ha*

A total of 14 trials were reviewed on Alternaria leaf blight of carrot (*Alternaria dauci*); 5 from northern states (Michigan, New York, New Jersey) and 9 from southern states (Florida, Texas, California). In trials with moderate to high disease pressure, BAS 510 applied alone at 224 g a.i./ha provided good control of leaf blight, comparable to pyraclostrobin and chlorothalonil.

In one trial from Texas, powdery mildew (*Erysiphe polygoni*) was assessed on a 0–10 scale of severity and BAS 510 at 224 g a.i./ha provided moderate control (50%). One trial is insufficient and due to low efficacy for this disease on other crops, additional supporting trials are needed for carrots.

The data support a claim for control of Alternaria leaf blight on carrots as proposed (220 g a.i./ha).

7.1.4.1.10 Stone fruit

Alternaria leaf spot *Alternaria* spp.	370 g/ha	*260 g a.i./ha*
Powdery mildew *Sphaerotheca* spp., *Podosphaera* spp.	370 g/ha	*260 g a.i./ha*
Brown rot, blossom blight *Monilinia* spp.	370 g/ha	*260 g a.i./ha*

Six trials assessed BAS 510 control of Monilinia blossom blight on stone fruit blossoms or twigs. Four of these trials showed adequate disease pressures (44–61% disease incidence); three trials conducted on cherry and one on nectarine. For the three cherry trials, all applied BAS 510 three times at a rate of 200 g a.i./ha, but the application interval ranged from 4–14 days. Under the highest disease pressures, BAS 510 provided 51% disease control when applied on a 4–6 day application interval. In other cherry studies, BAS 510 provided 54 and 91% control of shoot incidence, slightly better than myclobutanil in one trial. The final study on nectarine assessed trees for the percent twig blight at harvest. There were no differences in disease control between rates of 224 and 392 g a.i./ha. This suggests that the lower rate of 224 g a.i./ha is as effective as the higher rates. The first two applications were made at 14-day intervals, while the final three were made as 7-day intervals later in the growing season. The proposed application rate of 260 g a.i./ha was not tested in this trial, but is represented by 224 g results.

Brown rot fruit infections were assessed in five trials. Disease pressures for most of these were moderate; ranging from 55% disease incidence to 68% disease severity. BAS 510 formulations provided good to excellent control (66% reduction of disease incidence and 83–90% reduction of disease severity) when applied at the recommended rate (260 g a.i./ha) after two to three applications, seven days apart. For studies that tested lower application rates, it appeared that 224 g a.i./ha gave similar control compared to higher rates (280 to 392 g a.i./ha); however, only one study tested this lower rate.

Eleven storage trials were conducted on peach fruit. In most trials, the fruit was inoculated upon entering storage and then rated between 4 and 12 days later. Of the trials conducted under moderate to high disease conditions, it was noted that BAS 510 at the proposed rate provided moderate disease control (22 to 68%), when rated after at least one week after harvest with approximately 7–14 day PHI. Studies with a three-day PHI showed greater levels of control (81–95% reduction in disease severity), if assessed after a four-day storage interval although these assessments were not conducted on a second date, and disease pressures for the untreated fruit were low to moderate (27%). Lower application rates did not consistently provide disease control equal to the proposed rate, confirming that 260 g a.i./ha of BAS 510 02F is needed.

For the claim of Alternaria leaf spot, the applicant clarified that the intended pathogen was *Blumeriella jaapii*. No data from Canada or the U.S. were submitted on this pathogen to support the leaf spot claim. No data from Canada or the U.S. were submitted for powdery mildew on stone fruit.

The data support a claim for control of blossom blight and brown rot of stone fruit as proposed (260 g a.i./ha).

Due to the general nature of *Monilinia* spp. in stone fruit crops, accepted claims for cherry, nectarine and peach can be extended to other listed crops as proposed.

7.1.4.1.11 Berries

Botrytis gray mould *Botrytis cinerea*	560 g/ha *390 g a.i./ha*

No data were submitted to support claims for Alternaria leaf spot, powdery mildew, Botrytis gray mould or mummy berry of small berries. Based on similar pathology of *Botrytis cinerea* and the same proposed use rate (390 g a.i./ha), data on strawberries can be used to support the claim of gray mould, with the same PHI, on berries.

There are no data on berries which would confirm that the application rate for BAS 510 02F derived from strawberry data is appropriate for all types of berries in this group. Based on the similar pathology of *Botrytis cinerea* on berry crops, the proposed rate of 390 g a.i./ha is accepted; however, trials on the major crops in this group, blueberry and raspberry, are required as a condition of temporary registration to confirm this rate.

7.1.4.1.12 Grapes

Powdery mildew *Uncinula necator*	315 g/ha *220 g a.i./ha*
Botrytis gray mould *Botrytis cinerea*	560 g/ha *390 g a.i./ha*

Reports of 12 trials on powdery mildew of grapes (*Uncinula necator*) were submitted from California and Oregon. Incidence or severity of powdery mildew was assessed on leaves and berry clusters. BAS 510 usually provided acceptable control on leaves (96%) and berries (95%) under moderate to high pressure, although its efficacy was less consistent than that of the strobilurins. BAS 510 was applied preventatively at intervals of 8–24 days and using 4–7 applications. In comparative trials, 14-day intervals were more effective than 21-day intervals for fungicides in general. BAS 510 was applied at 224 to 392 g a.i./ha but the difference in efficacy between the rates was not statistically significant, so the proposed rate of 220 g a.i./ha is acceptable.

Three trials from Michigan were submitted in support of Botrytis gray mould control by BAS 510. Disease reduction of 60–70% was considered acceptable and comparable to commercial standards iprodione, dithane and kresoxim-methyl; however, control with BAS 510 varied from 14 to 93%, irrespective of rate. Disease pressure was not high and only one trial assessed the proposed rate of 390 g a.i./ha, the rest were at least 560 g. As there are insufficient trials at the proposed rate and this is not within the range to be applied for powdery mildew, additional trials are required to better define the rate for Botrytis control on grape.

The data support a claim for control of powdery mildew of grapes, as proposed (220 g a.i./ha). Additional trials are required to support a claim for Botrytis gray mould control, which is not accepted.

7.1.4.1.13 Strawberries

Botrytis gray mould *Botrytis cinerea*	560 g/ha *390 g a.i./ha*

Botrytis gray mould was assessed in 23 trials mostly from California, but also in North Carolina and Pennsylvania. BAS 510 was applied at 403–784 g a.i./ha and typically provided excellent control (>90%) comparable to vinclozolin and better than iprodione or captan. There was no apparent rate effect within the range tested, although only 8 trials tested BAS 510 at close to the proposed rate (412 g or less). In some trials, control was as low as 60–80% or none of the fungicides were effective but this was not apparently related to differences in rate or disease pressure.

Treatments were applied every 6–21 days, with 4 to 7 applications. A 7-day interval was most typical, and in one comparative trial, both BAS 510 and the standard treatment were more effective when applied at 7 day than 14 or 21 days intervals. However, a 14 day interval was effective in other trials and is also acceptable. Disease was assessed several days after the most recent application. In one trial, berries were assessed 2–4 days post-harvest and may have been sprayed on the day of harvest, however there was no comparison with earlier spray dates to support this practice as necessary for efficacy.

The data support a claim for control of Botrytis gray mould on strawberries as proposed (390 g a.i./ha).

7.1.4.2 BAS 510 02F Turf Fungicide

7.1.4.2.1 Turf

Dollar spot *Sclerotinia homeocarpa*	4.0–5.5 g product/100 m^2 *280–390 kg a.i./ha*

There were 24 trials were conducted across 12 U.S. states, while 7 trials were conducted in Canada (Ontario and Quebec). Five varieties of turf were tested, with creeping bentgrass being the main turf type. Application rates ranged from 150 to 1592 g a.i./ha, and fungicides were applied from 1 to 5 times, on a schedule of 14 to 28 days.

The data support a claim for control of dollar spot on turfgrass with BAS 510 applied at a reduced rate of 3.2–4.0 g product/100 m^2 (224 to 280 g a.i./ha) every 14 days. The upper proposed rate of 5.5 g product/100 m^2 (385 g a.i./ha) was not justified and the longer proposed interval of 28 days was not shown to result in consistently acceptable control. Phytotoxicity on turf was not noted for any of the BAS 510 formulations in any of the trials.

BAS 510 02F has limited efficacy on turfgrass pathogens other than dollar spot and would potentially be used with other fungicide products. In the submitted trials, the only two tank mixes that were tested for compatibility were BAS 510 02F with pyraclostrobin or with an experimental product. Neither of these had an adverse effect on the turf. However the proposed general tank mix and additives statements should be removed as no other product combinations have been tested for compatibility.

7.1.5 Total spray volume

Not assessed, see Section 7.1.4.

7.2 Phytotoxicity to target plants (including different cultivars), or to target plant products

Phytotoxicity was not observed in the majority of efficacy trials for a wide range of crops and conditions, except for individual incidents on grape, peach and tomato. In grape trials, BAS 510 was not assessed alone, and the injury was attributed primarily to combination with other fungicides or miticides. A statement on the BAS 510 02F label advises against application of this product to Concord grapes due to the possibility of crop injury. Concord was not among the varieties tested in efficacy trials, although it is known to be susceptible to injury from other fungicides, so the statement is not unreasonable, provided that it is due to BAS 510 02F alone and not in combination with strobilurins. In the peach trial, all treatments caused slight leaf tip burn but no further damage. On tomatoes there was a yield reduction with increased BAS 510 02F rate in two trials; however, the trend was not statistically significant nor was it interpreted by researchers as due to crop injury. These effects were not found in any of the other trials on these same crops.

7.3 Observations on undesirable or unintended side effects

Observations on beneficials and other non-target organisms, on succeeding crops, other plants or parts of treated plants used for propagating purposes (e.g., seed, cutting, runners), were not reported in efficacy trials for BAS 510 02F products.

7.3.1 Impact on succeeding crops

Potential crops for rotation with BAS 510 02F-treated plants include cereals, canola, corn, soybeans, pulses, forages and vegetables. The fruit crops listed on the BAS 510 02F label are perennials and not subject to short-term rotation. Many of the potential crops used for rotation have been assessed for efficacy claims on the BAS 510 02F label, by one or more applications to foliage and fruit beginning at midseason, without adverse effects (see Section 7.2). It should be noted, however, that all treatments were applied as foliar sprays to maturing plants. Therefore, the potential for adverse effects of BAS 510 02F soil residues on emerging seedlings of subsequent (rotational) crops or non-target plants was not evaluated in these trials.

7.3.2 Impact on adjacent crops

Not assessed, see Section 7.3.1.

7.4 Economics

Not assessed.

7.5 Sustainability

7.5.1 Survey of alternatives

7.5.1.1 Non-chemical control practices

The proposed control claims pertain to diseases which affect foliage, flowers and fruit of the proposed food crops and turf. Non-chemical control practices for these diseases may include use of resistant or tolerant varieties, disease avoidance by altering planting dates, rotation with non-host crops and removal of infested crop debris. Management of the crop canopy by planting, thinning, mowing or pruning can also contribute by reducing leaf wetness or humidity, which favour disease.

7.5.1.2 Chemical control practices

Table 7.5.1 Alternative disease control products

Crop	Diseases	Active ingredients
Canola	Sclerotinia stem rot Black spot	azoxystrobin, iprodione, propiconazole, vinclozolin
Dry bean group	White mould	thiophanate-methyl, vincolozolin
Chickpeas	Ascochyta blight White mould Gray mould	azoxystrobin, chlorothalonil, carbathiin + thiabendazole, pyrachlostrobin
Lentils	Ascochyta blight White mould Gray mould	azoxystrobin, chlorothalonil, mancozeb, carbathiin + thiabendazole, pyraclostrobin
Succulent bean group	White mould Gray mould	iprodione
Lettuce	Lettuce drop Botrytis rot Rhizoctonia bottom rot—suppression	iprodione, vinclozolin

Crop	Diseases	Active ingredients
Fruiting vegetable group	Early blight Septoria leaf spot Powdery mildew Botrytis gray mould	captan, chlorothalonil, copper sulphate, cymoxanil, mancozeb, maneb, metiram, pyraclostrobin, ziram
Potatoes	Early blight White mould	captan, chlorothalonil, cymoxanil, dimethomorph, famoxadone, mancozeb, metiram, propamocarb hydrochloride, pyraclostrobin, metalaxyl-M, zoxamide
Bulb vegetable group	Alternaria leaf blight Botrytis leaf blight	anilazine, fosetyl-al, iprodione, maneb, mancozeb, metalaxyl-M
Carrots	Alternaria leaf blight Powdery mildew	chlorothalonil, copper sulphate, iprodione, mancozeb, maneb, metiram
Stone fruit group	Alternaria leaf spot Powdery mildew Brown rot Monilinia blossom blight	captan, chlorothalonil, cyprodinil, fenhexamid, iprodione, myclobutanil, propiconazole, pyraclostrobin, thiophanate-methyl, triforine
Berry group	Alternaria leaf spot Powdery mildew Botrytis gray mould Mummy berry	anilazine, chlorothalonil, pyraclostrobin
Grape	Powdery mildew Botrytis gray mould	azoxystrobin, cyprodinil, fenhexamid, iprodione, myclobutanil, sulphur
Strawberry	Powdery mildew Botrytis gray mould	captan, chlorothalonil, fenhexamid, thiophanate-methyl, vinclozolin
Turf grass	Dollar spot	azoxystrobin, chlorothalonil, iprodione, myclobutanil, propiconazole, thiophanate-methyl

7.5.2 Compatibility with current management practices including integrated pest management

BAS 510 02F is approved for use on a wide range of field crops, vegetable crops, fruit crops and turf that are produced using regular fungicide as part of the disease management program. Integrated pest management (IPM) aspects for these crops may include disease, crop stage and weather monitoring, with the aim of reducing the number of fungicide applications, as well as for resistance management (see Section 7.5.4). BAS 510 02F will be integrated into existing fungicide application schedules in order to provide an effective alternative to currently registered fungicides and is expected to be compatible with current management practices.

7.5.3 Contribution to risk reduction

Not assessed.

7.5.4 Information on the occurrence or possible occurrence of the development of resistance

The Fungicide Resistance Action Committee (FRAC) considers boscalid to be one of the carboxamides (Group 7), a Medium Risk group, with resistance management required for certain pathogens for which resistance is known (*Ustilago* on barley and corn, *Puccinia* on chrysanthemum). There are no specific recommendations for Group 7 fungicides with respect to rotational sequence or maximum number of applications. Based on other Medium Risk groups; however, the proposed directions on the BAS 510 02F label, recommending no more than two consecutive applications of Group 7 fungicides before alternating to a fungicide having a different mode of action, are appropriate. These rotation directions are pertinent to multiple applications of BAS 510 02F on fruiting vegetables, potato, bulb vegetables, carrots, stone fruits, berries, grapes, strawberries and turf. Maximum number of applications is six or less, which is also acceptable for this active ingredient.

The proposed label statement indicating that BAS 510 02F is effective against pathogens resistant to other fungicides should be removed as it was not supported by sufficient tests with resistant isolates of the target pathogens. Baseline sensitivity data for BAS 510 02F have been collected for regular field isolates of *Botrytis cinerea*, *Sphaerotheca fulginea* and *Uncinula necator*, which may be used in future to measure potential shifts in resistance. BAS 510 02F does have a role as a suitable option in disease control programs with multiple fungicides and this may ultimately delay development of resistance to other fungicide groups.

7.6 Conclusions

Based on the submitted data and rationales, the following disease control claims on the BAS 510 02F Crop Fungicide label are supported: Canola—stem rot, Dry beans—white mould, Chickpea and lentil—ascochyta blight, white mould, gray mould, Succulent beans—white mould, gray mould, Head and leaf lettuce—suppression of lettuce drop (*Sclerotinia minor*), control of Botrytis rot, Fruiting vegetables—early blight, Botrytis gray mould, Potato—early blight, Bulb vegetables—Alternaria purple blotch, Botrytis leaf blight, Carrots—Alternaria leaf blight, Stone fruit—Monilinia blossom blight, brown rot, Grape—powdery mildew, Strawberry—Botrytis gray mould.

On the BAS 510 02F Turf Fungicide label, the use for control of dollar spot is supported; however, general statements on tank mixes should be removed.

In some cases, accepted application rates for these diseases differ from those proposed (see Table 7.6.1). Typically the efficacy data were not available on food crops to determine the necessity of applications on or close to day of harvest (0–1 day PHI); however, this may be commercial practice for crops with sequential harvesting.

Two claims on the BAS 510 02F Crop Fungicide label are accepted contingent upon confirmatory data:

- The claim of Botrytis gray mould control on berries can be supported provided that efficacy trials on blueberry, lowbush and raspberry are submitted as a condition of temporary registration to confirm the application rate.
- Aerial application to selected field crops is also accepted. Trials with low water volume applications by ground equipment suggested that aerial application of BAS 510 would be effective. Validating trials comparing aerial equipment and ground equipment on representative field crops (canola and one of the pulse crops) are required as a condition of temporary registration.

BAS 510 02F contains boscalid, one of the fungicide active ingredients in FRAC Group 7 (carboxamides). This group contains few registered products in North America and has no specific resistance-management guidelines. The resistance strategy on the proposed label is considered adequate but should be placed within standard statements as per Regulatory Directive DIR99-06. Label revisions are required under General information, Directions for use (Rate tables), Aerial application, Tank mixing information and Resistance management.

Table 7.6.1 Summary of accepted disease control claims

Crop/Pest	Rate g/ha *g a.i/ha*	Directions
Canola		
Sclerotinia stem rot *Sclerotinia sclerotiorum*	350 *250*	Apply at 20–50% flowering. Apply a second time 7–14 days later up to 50% bloom, if disease persists, or weather conditions are favourable for disease development. May be applied by air. 2 applications

Crop/Pest	Rate g/ha g a.i/ha	Directions
Dry shelled pea and bean (except soybean) [delete lablab and guar]		
White mould *Sclerotinia sclerotiorum*	560–770 *390–540*	Apply at 20–50% flowering and again 7–14 days later if disease persists or weather favours disease. Use high rate for extended protection and maximum yield benefit. May be applied by air. 2 applications
Chickpea and lentil		
Ascochyta blight *Ascochyta* spp.	420 *290*	Apply at beginning of flowering and again 7–14 days later if disease persists or weather favours disease. May be applied by air. 2 applications
White mould *Sclerotinia sclerotiorum*		
Gray mould *Botrytis cinerea*		
Succulent beans		
White mould *Sclerotinia sclerotiorum*	560–770 *390–540*	Apply at 20–50% flowering and again 7–14 days later if disease persists or weather favours disease 2 applications
Gray mould *Botrytis cinerea*	420 *290*	
Head and leaf lettuce		
Lettuce drop *Sclerotinia minor* *Sclerotinia sclerotiorum*	385 *270*	Direct seeded lettuce—apply immediately after thinning (within 2 days) and again 10–20 days later if conditions continue to favour disease. Transplanted lettuce—apply 7–10 days after transplanting and again 10–20 days later. Use high rate when disease pressure is high. Ensure coverage of lower portion of plant and surrounding soil surface. 2 applications
Botrytis rot *Botrytis cinerea*	385 *270*	

Crop/Pest	Rate g/ha g a.i/ha	Directions
Fruiting vegetable group		
Early blight *Alternaria solani*	175–315 *120–220*	Apply prior to disease development and at 7–10 day intervals. Use high rate and shorter interval when disease pressure is high. 5 applications/season with a maximum of 2 applications for Botrytis control
Botrytis gray mould *Botrytis cinerea*	420 *290*	
Potato		
Early blight *Alternaria solani*	175–315 *120–220*	Apply prior to disease development and at 14-day intervals if conditions continue to favour disease. 4 applications
Bulb vegetables [delete chives]		
Alternaria purple blotch *Alternaria porri*	475 *330*	Apply prior to disease development and at 7–14 day intervals. Use shorter interval when disease pressure is high. 6 applications
Botrytis leaf blight *Botrytis squamosa*		
Carrots		
Alternaria leaf blight *Alternaria dauci*	315 *220*	Apply prior to disease development and at 7–14 day intervals. Use shorter interval when disease pressure is high. 5 applications
Stone fruit group		
Brown rot Blossom blight *Monilinia* spp.	370 *260*	Apply from pink bud or prior to disease development and continue at 7–14 day intervals. Use shorter interval when disease pressure is high. 5 applications
Berry group		
Botrytis gray mould *Botrytis cinerea*	560 *390*	Apply prior to disease development and continue at 7–14 day intervals. Use shorter interval when disease pressure is high. 4 applications

Crop/Pest	Rate g/ha *g a.i/ha*	Directions
Grape		
Powdery mildew *Uncinula necator*	315 *220*	Apply from bud break and at 10–14 day intervals. 5 applications
Strawberry		
Botrytis gray mould *Botrytis cinerea*	560 *390*	Apply prior to disease development and continue at 7–14 day intervals. Use shorter interval when disease pressure is high. 5 applications
Turf		
Dollar spot *Sclerotinia homeocarpa*	320–400 *224–280*	Apply when local conditions favour development of disease. Apply in 500–1500 L water/ha. Use the higher rate when prolonged favourable conditions exist. Application interval every 14 days. Maximum 2.4 kg/ha per hectare per season.

8.0 Toxic Substances Management Policy considerations

During the review of BAS 510 F products, the PMRA has taken into account the federal *Toxic Substances Management Policy*[1] and has followed its Regulatory Directive DIR99-03[2]. It has been determined that BAS 510F is not a TSMP Track 1 substance.

- BAS 510 F meets the criteria for persistence. Its DT_{50} values in soil (585 day Canadian field study) and sediment (no decline) are above the TSMP Track 1 cut-off criteria (≥ 182 and ≥ 365 days, respectively). Its DT_{50} value in water (up to nine days due to partitioning to sediment) is below the TSMP Track 1 cut-off criterion of ≥ 182 days). BAS 510 F is unlikely to volatilize, based on the vapour pressure and Henry's Law constant. Therefore, a study of persistence in air is not triggered.

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[1] The federal *Toxic Substances Management Policy* is available through Environment Canada's Web site at: www.ec.gc.ca/toxics

[2] The *Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*, DIR99-03, is available through the Pest Management Information Service. Phone: 1-800-267-6315 within Canada or 1-613-736-3799 outside Canada (long distance charges apply); Fax: 1-613-736-3798; E-mail: pmra_infoserv@hc-sc.gc.ca or through our Web site at www.hc-sc.gc.ca/pmra-arla

- BAS 510 F does not meet the criteria for bioaccumulation. Studies have shown that the BCF is a maximum of 105 in inedible fish tissue, which is below the TSMP Track 1 cut-off criterion of ≥5000. There was no evidence of accumulation of BAS 510 in a biokinetic study with rats.

- The toxicity of BAS 510 F is described in sections 3.5, 4.2 and 6.4.

- BAS 510 F does not form any major transformation products under field conditions.

- BAS 510 F (technical grade) contains manufacturing by-products (microcontaminants). 1,2,3,4,6,7,8-heptachlorooxanthrene (HpCDD) microcontamination was detected at 1.8 ppt in one out of five **pilot** batches analyzed and octachlorooxanthrene (OCDD) was detected at 9.3 and 1.8 ppt, respectively, in two out of five batches. All other 2,3,7,8-substituted oxanthrenes were not detected in all 5 batches at the limit of quantitation (LOQ) of 4 ppt for 2,3,7,8-tetrachlorooxanthrene, 0.7 ppt for pentachlorooxanthrene, 1 ppt for total hexachlorooxanthrene, 1.2 ppt for HpCDD and 2.4 ppt for OCDD. Analysis of representative batches of full scale production for microcontamination will be required, when technical material from the full scale process is available.

- The technical also contains an impurity, 4'-chloro[1,1'-biphenyl]-2-amine (CAS #1204-44-0), at a concentration of 30 mg/kg (ppm). An experimentally determined log K_{ow} of this impurity is required. Additional impurities might be identified pending submission of full scale production samples.

- The products (BAS 510 02 F crop and turf fungicides) do not contain any formulants that are known to be TSMP Track 1 substances. All formulants are either USEPA list 3 or list 4A/B.

9.0 Regulatory decision

The active ingredient boscalid (BAS 510) and associated end-use products, BAS 510 02F Crop Fungicide and BAS 510 02F Turf Fungicide, have been granted temporary registration pursuant to section 17 of the Pest Control Products Regulations for the control of the following:

- Sclerotinia stem rot on canola;
- White mould on dried bean;
- Ascochyta blight, White mould and Gray mould on chickpeas and lentils;
- White mould and Gray mould on succulent beans;
- Lettuce drop (suppression) and Botrytis rot on lettuce (head and leaf);
- Early blight and Botrytis gray mould on the fruiting vegetable crop group (Crop Group 8, which includes eggplant, ground cherries, peppers [all varieties], tomatilo and tomato);

- Early blight on potato;
- Alternaria purple blotch and Botrytis leaf blight on the bulb vegetable crop group (Crop Group 3, which includes onions, dry bulb and green, garlic, leek and shallots);
- Alternaria leaf blight on carrots;
- Brown rot and Blossom blight on the stone fruit crop group (Crop Group 12, which includes apricots, cherry [sweet and tart], nectarine, peaches, plums, prunes and plumcotts);
- Botrytis gray mould on the small berry crop group (Crop Group 13, which includes blackberry, raspberry, current, elderberry, blueberry [highbush only] gooseberry, huckleberry, loganberry);
- Powdery mildew on grapes;
- Botrytis gray mould on strawberries; and
- Dollar spot on golf course turfgrass.

The previous is subject to the generation of the following studies:

- Log K_{ow} of the impurity, 4'-chloro[1,1'-biphenyl]-2-amine (CAS # 1204-44-0)
- Concentrations of BAS 510F in plant pollen/nectar
- Effects of formulated BAS 510F on parasitoids and predatory mites
- EC_{25} of formulated BAS 510F for vegetative vigour and seedling emergence of non-target terrestrial plants
- Dermal sensitization
- Developmental neurotoxicity (Rat)
- Acute oral toxicity
- Primary dermal irritation
- Analytical methods
- Radiovalidation
- Final report of the storage stability study in plant matrices
- Stability data in processed food
- Residue
- Efficacy

List of abbreviations

a.i.	active ingredient
AD	administered dose
ADI	acceptable daily intake
ALAT	alanine aminotransferase
ALP	alkaline phosphatase
ARfD	acute reference dose
ARTF	Agricultural Re-entry Task Force
ATP	adenosine triphosphate
BCF	bioconcentration factor
bw	body weight
bwg	body-weight gain
BWI	body weight of individual(s)
CAS	Chemical Abstracts Service
Cmax	peak plasma concentration
CSFII	Continuing Survey of Food Intakes by Individuals
CYP450	cytochrome P450
d	day(s)
DFR	dislodgeable foliar residue
DI	daily intake
DNA	deoxyribonucleic acid
dw	dry weight
EEC	estimated environmental concentration
EROD	ethoxyresorufin-O-deethylase
F	female
FC	food consumption
F_0	parental animals
F_1	1st generation offspring
F_2	2nd generation offspring
FID	flame ionization detector
FOB	functional observational battery
FRAC	Fungicide Resistance Action Committee
GC	gas chromatography
GD	gestation day
GIT	gastrointestinal tract
GGT	gamma (γ) glutamyl transferase
GLP	good laboratory practices
GPMT	guinea pig maximization test
GSD	geometric standard deviation
HD	high dose
HDT	highest dose tested
HPLC	high-performance liquid chromatography
HpCDD	1,2,3,4,6,7,8-heptachlorooxanthrene
ILV	independent laboratory validation
ind	individual

K_d	adsorption coefficient
K_{oc}	organic carbon adsorption coefficient
K_{ow}	octanol–water partition coefficient
LC_{50}	lethal concentration 50%
LD_{50}	lethal dose 50%
LD	low dose
LOAEL	lowest observed adverse effect level
LOQ	limit of quantitation
MIS	maximum irritation score
MAS	maximum average score
M/L/A	mixers, loaders, applicators
MMAD	mass median aerodynamic diameter
MOE	margin of exposure
MOS	margin of safety
MRL	maximum residue limit
NA	not applicable
NAFTA	North American Free Trade Agreement
NAFTA TWG	North American Free Trade Agreement's Technical Working Group on Pesticides
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
OCDD	octachlorooxanthrene
ORETF	Outdoor Residential Exposure Task Force
PAI	pure active ingredient
PC	positive control
PCP	pest control product
PHED	Pesticide Handlers Exposure Database
PHI	preharvest interval
p*K*a	dissociation constant
PMRA	Pest Management Regulatory Agency
PND	post-natal day
ppm	parts per million
PROD	pentoxyresorufin-O-deethylase
RSD	relative standard deviation
SER	smooth endoplasmic reticulum
SIM	selected ion monitoring
T3	tri-iodothyronine
T4	thyroxine
TC	transfer coefficient
TGAI	technical grade active ingredient
TMCF	theoretical maximum concentration factor
TRR	total radioactive residue
TSH	thyroid stimulating hormone
TS	test substance
TSMP	*Toxic Substances Management Policy*
TTR	turf transferrable residue
UDS	unscheduled deoxyribonucleic acid synthesis

μg	micrograms
μL	microlitre
USEPA	United States Environmental Protection Agency
UV	ultraviolet
wt	weight

Appendix I Chemistry

Table 1 Analytical methods for analysis of the active substance as manufactured

Product	Analyte	Method type	Linearity range	Recovery (%)	RSD (%)	LOQ (%)	Method
Technical	Boscalid	HPLC-UV	8–24 mg/L	99.8	9.46	Not required	Accepted
Technical	Major impurities	HPLC-UV	0.8–40 mg/L	97.8–108.1	3.9–4.24	<0.05	Accepted

Table 2 Analytical methods for formulation analysis

Product	Analyte	Method ID	Method type	Mean recovery (%) (n)	RSD (%)	Method
BAS 510 02	Boscalid	F-96	GC-FID	97.97 (9)	0.77	Accepted

Appendix II Toxicology

RAT METABOLISM (oral)—BAS 510 F Technical

Absorption: following oral administration, ^{14}C-BAS 510 F rapidly absorbed, peak plasma concentration achieved within 8 h following LD (50 mg/kg bw) and HD (500 mg/kg bw); absorption was approx. 56% of AD following LD administration and decreased to approx. 14–17% AD following HD; following HD administration, Cmax not increased proportionately to AD compared to LD exposure suggesting saturation of absorption at HD; decreased urinary and biliary excretion and increased fecal excretion noted following HD also consistent with saturation of absorption.
Distribution: at sacrifice (168 hours post-dosing), highest tissue levels noted in thyroid and bone marrow; however, mean recovery of radioactivity in tissue/carcass at sacrifice was low, less than 0.2% of AD, indicating little potential for accumulation of BAS 510 F or any of its metabolites; tissue burdens were also slightly higher in organs/tissues associated with absorption, metabolism and elimination processes including liver, kidney and gut.
Excretion: major route of excretion via feces (approx. 80–85% of AD following LD and greater than 90% of AD following HD); urinary excretion accounted for approx. 15–17% of AD following LD and approx. 3–5% of AD following HD; within 48 h biliary excretion accounted for approx. 39–40% of AD following LD and approx. 11–12% of AD following HD; majority of AD eliminated within 24–48 h (greater than 85% AD excreted by 48 h); no radioactivity detected in exhaled air.
Metabolism: rapidly and extensively metabolised; metabolites (hydroxylation and conjugation products) were consistent with Phase I oxidation reactions followed by Phase II conjugation processes; major urinary metabolites identified as M510F01 (approx. 10–16 and 0.5–2.2% of AD following LD and HD, respectively) and its glucuronic acid conjugate M510F02 (approx. 3–4 and 0.1–3 % of AD following LD and HD, respectively); traces of parent compound detected in urine following repeat HD only (less than 0.11% of AD); minor urinary metabolites identified as M510F48, M510F05, M510F03, M510F04, M510F12, M510F20 and M510F42 (less than 2% of AD); traces of M510F47 (chloronicotinic acid) identified following HD (less than 0.1% of AD); in feces the parent compound was the predominant component (approx. 30–40 and 60–85% of AD following LD and HD respectively), major metabolites were identified as M510F01 (approx. 19–22 and 4–9% of AD following LD and HD, respectively) and M510F06 (approx. 5–8 and 1–2% of AD following LD and HD, respectively); in bile major metabolites identified as M510F02 (approx. 20 and 5% of AD following LD and HD, respectively) and M510F05 (approx. 14 and 4% of AD following LD and HD, respectively); minor biliary metabolites identified as M510F01, M510F57 and M510F58, however, none accounted for more than 2% of AD.

Absorption, distribution and excretion did not appear to be significantly influenced by repeat high-dose oral administration, gender or position of the label. Slight gender differences were noted in the metabolite profile.

STUDY	SPECIES, STRAIN AND DOSES	NOAEL & LOAEL mg/kg bw/day	TARGET ORGAN, SIGNIFICANT EFFECTS, COMMENTS
ACUTE STUDIES—BAS 510 F TECHNICAL			
Oral	5 Wistar chbb:thom (SPF) rats/sex/dose **Dose Level**: 2000 or 5000 mg/kg bw	LD$_{50}$ greater than 5000 mg/kg bw for both sexes	No treatment-related mortality, necropsy findings or changes in bw in either sex. No clinical signs at 2000 mg/kg bw; clinical signs at 5000 mg/kg bw including impaired general state, dyspnea, staggering, erythema and piloerection; completely resolved by day 2. **LOW TOXICITY**
Dermal	5 Wistar chbb:thom (SPF) rats/sex **Dose Level**: 2000 mg/kg bw	LD$_{50}$ greater than 2000 mg/kg bw for both sexes	No mortality; no treatment-related clinical signs or necropsy findings; all males and 2/5 females gained wt, remaining females lost wt (2 g each). **LOW TOXICITY**

STUDY	SPECIES, STRAIN AND DOSES	NOAEL & LOAEL mg/kg bw/day	TARGET ORGAN, SIGNIFICANT EFFECTS, COMMENTS
ACUTE STUDIES—BAS 510 F TECHNICAL			
Eye Irritation	New Zealand White rabbits (2 males/4 females) **Dose Level**: 0.1 mL (approximately 21 mg)	MIS: 2.0/110 at 1 and 24 h MAS (for 24, 48 and 72 h): 0.8/110	Conjunctival redness at 1 h, resolved in 5/6 at 48 h and in remaining animal by 72 h. No corneal or iridial changes. **MINIMALLY IRRITATING**
Skin Irritation	New Zealand White rabbits (2 males/4 females) **Dose Level**: 0.5 g	MIS: 1.0/8 at 1 h MAS (for 24, 48 and 72 h): 0.17/8	Very slight to well defined erythema in 5/6 animals at 1 h, resolved in 2 animals by 24 h and in remaining animals by 48 h; no edema present. **SLIGHTLY IRRITATING**
Skin Sensitization (GPMT method of Magnusson and Kligman)	Pirbright White, Dunkin Hartley Crl: (HA)BR guinea pigs Test Group: 20 females Control Group: 2 groups of 10 females/group **Induction**: Intradermal: 5% (w/w) Percutaneous: 25% (w/w) **Challenge**: 5% (w/w)	Intradermal induction slight to well-defined signs of skin irritation all test animals. Percutaneous induction: erythema and edema with incrusted and partially open skin lesions in all test and control animals. Challenge: very slight erythema noted in 3/19 and 4/19 test group animals at 24 and 48 h, respectively.	Under the conditions of this study, BAS 510 F was not considered to be skin sensitizer, however, the dose level used for challenge treatment was not considered to be adequate. In the absence of an adequate dermal sensitization study, it is recommended that BAS 510 F be classified as a **Potential skin sensitizer**.
ACUTE STUDIES—BAS 510 02 F CROP FUNGICIDE/BAS 510 02 TURF FUNGICIDE			
Oral—limit dose	3 Wistar (SPF)/Crl:WI (GLX/BRL/HAN)IGS BR rats/sex **Dose Level**: 2000 mg/kg bw	**LD_{50}**: greater than 2000 mg/kg bw/d	No mortality; no treatment-related clinical observations, necropsy findings or changes in bw. **LOW TOXICITY**
Dermal—limit dose	5 Wistar (SPF)/Crl:WI (GLX/BRL/HAN)IGS BR rats/sex **Dose Level**: 2000 mg/kg bw	**LD_{50}**: greater than 2000 mg/kg bw/d	No mortality; no treatment-related clinical observations, necropsy findings or changes in bw. **LOW TOXICITY**
Inhalation	5 Wistar (SPF)/Crl:WI (GLX/BRL/HAN)IGS BR rats/sex **Dose Level**: Analytical: 5.4 mg/L MMAD: 4.2/4.2 μm, GSD = 2.5/3.0	**LC_{50}**: greater than 5.4 mg/L	No mortality; no treatment-related necropsy findings or changes in bw; clinical signs included squatting posture and accelerated respiration, resolved by day 3. **LOW TOXICITY**
Skin Irritation	3 male New Zealand White rabbits **Dose Level**: 500 mg	MIS: 0.3/8 at 1 h MAS (for 24, 48 and 72 h): 0/8	Very slight erythema (grade 1) noted in 1/6 animals at 1 h, resolved by 24 h. **Minimally irritating**

STUDY	SPECIES, STRAIN AND DOSES	NOAEL & LOAEL mg/kg bw/day	TARGET ORGAN, SIGNIFICANT EFFECTS, COMMENTS
Eye Irritation	3 male New Zealand White rabbits **Dose Level**: 100 mg	MIS: 15.7/110 at 24 h. MAS (for 24, 48 and 72 h): 10.6/110.	Mildly irritating to eye based on MIS at 24 h, however, based on persistence of conjunctival findings up to and including day 17, recommended that classification be upgraded to **Moderately irritating**.
Skin Sensitization (Modified Buehler)	30 young adult Hartley Crl: (HA) BR guinea pigs Test group: 10/sex Control group: 5/sex **Dose Level**: 40% (w/w) for both the induction and challenge treatments	Induction: discrete to moderate confluent erythema observed in few test animals. 1st challenge: discrete to moderate erythema in one test animal at 24 and 48 h. 2nd challenge: no erythema observed in either group.	Under the conditions of this study, BAS 510 02 F Crop Fungicide was not considered to be a skin sensitizer, however, the dose level used for induction and challenge treatment was not considered to be adequate. In the absence of an adequate dermal sensitization study, it is recommended that BAS 510 02 F Crop Fungicide be classified as a **Potential skin sensitizer**.
SHORT TERM TOXICITY—BAS 510 F TECHNICAL			
90-day dietary —mouse	10 C57BL mice (C57BL/6JRj)/sex/dose **Dose Levels**: 0, 150, 1000, 4000, or 8000 ppm (equal to 0/0, 29/42, 197/277, 788/1184 and 1518/2209 mg/kg bw/d for M/F)	**NOAEL**: Males: 1000 ppm (197 mg/kg bw/d) Females: 8000 ppm (2209 mg/kg bw/d) **LOAEL**: Males: 4000 ppm (788 mg/kg bw/d). Females: not determined	4000 ppm: increased liver wt and minimal to marked/severe fatty changes in liver (M). 8000 ppm: increased liver wt and minimal to marked/severe fatty changes in liver (M). **Control wk 13 bw** M: 28.9 g F: 22.5 g **Control wk 13 daily food cons.**: M: 4.9 g/animal F: 6.1 g/animal
90-day dietary —rat	10 Wistar rats/sex/dose **Dose level**: 0, 100, 500, 2000, 5000 or 15 000 ppm (equal to 0/0, 7/8, 34/40, 137/159, 347/395 and 1055/1225 mg/kg bw/d for M/F)	**NOAEL**: Males: 500 ppm (34 mg/kg bw/d). Females: 2000 ppm (159 mg/kg bw/d). **LOAEL**: Males: 2000 ppm (137 mg/kg bw/d). Females: 5000 ppm (395 mg/kg bw/d).	2000 ppm: increased thyroid wt (M); diffuse hyperplasia and hypertrophy follicular epithelial cells in thyroid (M). 5000 ppm: increased thyroid wt (M/F); diffuse hyperplasia and hypertrophy follicular epithelial cells in thyroid (M) 15 000 ppm: increased thyroid wt (M/F); diffuse hyperplasia and hypertrophy follicular epithelial cells in thyroid (M). **Control wk 13 bw** M: 462 g F: 259 g **Control wk 13 daily food cons.**: M: 21.4 g/animal F: 15.7 g/animal
90-day dietary —dog	5 Beagle dogs/sex/dose **Dose Levels**: 0, 250, 2500 or 25 000 ppm (equal to 0/0, 7.6/8.1, 78/82 and 729/824 mg/kg bw/d for M/F).	**NOAEL**. 250 ppm (7.6/8.1 mg/kg bw/d for M/F) **LOAEL**: 2500 ppm (78.1/81.7 mg/kg bw/d for M/F)	2500 ppm: increased ALP activity, serum triglycerides and liver wt (M/F), no histopathological findings in liver. 25 000 ppm: increased ALP activity, serum triglycerides and liver wt (M/F); increased thyroid wt (F), no histopathological findings in liver or thyroid.

STUDY	SPECIES, STRAIN AND DOSES	NOAEL & LOAEL mg/kg bw/day	TARGET ORGAN, SIGNIFICANT EFFECTS, COMMENTS
12-month dietary—dog	5 Beagle dogs/sex/dose **Dose Levels**: 0, 200, 800, 2000 or 20 000 ppm (equal to 0/0, 5.5/5.8, 22/22, 57/58 and 544/593 mg/kg bw/d for M/F).	**NOAEL**: 800 ppm (21.8/22.1 mg/kg bw/d M/F) **LOAEL**: 2000 ppm (57.4/58.3 mg/kg bw/d M/F)	2000 ppm: increased ALP activity, serum triglycerides and liver wt (M); increased thyroid wt (M); no histopathology in liver or thyroid 20 000 ppm: increased ALP activity, serum triglycerides and liver wt (M/F); increased thyroid wt (M/F); no histopathology in liver or thyroid.
28-day repeat dose dermal—rat (6 h/d, 5 d/wk)	10 Wistar rats/sex/dose **Dose Levels**: 0, 100, 250 or 1000 mg/kg bw/d.	**Systemic Toxicity**: **NOAEL**: 1000 mg/kg bw/d. **LOAEL**: not determined. **Local Dermal Irritation**: **NOAEL**: 1000 mg/kg bw/d **LOAEL**: not determined.	**Systemic Toxicity**: no adverse treatment-related signs of systemic toxicity at any dose level up to and including 1000 mg/kg bw/d, HDT. **Local Dermal Irritation**: no treatment-related signs of local dermal irritation at any dose level up to and including 1000 mg/kg bw/d, HDT.
CHRONIC TOXICITY AND ONCOGENICITY—BAS 510 F TECHNICAL			
18-month dietary—mice	50 CD-1 C57BL/6J Rj mice/sex/dose **Dose Levels**: 0, 80, 400, 2000 or 8000 ppm (equal to 0/0, 13/18, 65/90, 331/443 and 1345/1804 mg/kg bw/d for M/F)	**NOAEL**: Males: 400 ppm (65 mg/kg bw/d) Females: 2000 ppm (443 mg/kg bw/d) **LOAEL**: Males: 2000 ppm (331 mg/kg bw/d) Females: 8000 ppm (1804 mg/kg bw/d)	≥2000 ppm: lower bw and bwg (M). 8000 ppm: lower bw and bwg (F); oval cell proliferation (F). No significant difference between controls and treated groups in incidence of tumours, in total number of animals with tumours, in the incidence of benign and malignant tumours nor in number of tumour-bearing animals and no effect on time-dependence of occurrence of tumours. Under conditions of study there were no findings to indicate that BAS 510 F was oncogenic at any dose level up to and including 8000 ppm, the HDT. Dosing considered adequate.

STUDY	SPECIES, STRAIN AND DOSES	NOAEL & LOAEL mg/kg bw/day	TARGET ORGAN, SIGNIFICANT EFFECTS, COMMENTS
2-year dietary—chronic toxicity rats	20 Wistar rats/sex/dose **Dose Levels**: 0, 100, 500, 2500, or 15 000 ppm (equal to 0/0, 4.4/5.9, 21.9/30.0, 110/150 and 739/1000 mg/kg bw/d for M/F)	**NOAEL**: 500 ppm (21.9/30.0 mg/kg bw/d for M/F) **LOAEL**: 2500 ppm (110.0/150.3 mg/kg bw/d for M/F)	2500 ppm: increased thyroid wt (M/F); thyroid gland foci and enlargement (M); diffuse follicular cell hypertrophy and focal follicular cell hyperplasia in thyroid (M/F). 15 000 ppm: all animals sacrificed at approx. 17 months due to excessive toxicity (severe effects on bw) without further examinations. Thyroid follicular cell adenomas noted in 0/20, 0/20, 2/20 and1/20 males at 0, 100, 500 and 2500 ppm and 0/20, 0/20,1/20, 0/20 females at 0, 100, 500 and 2500 ppm, respectively; incidence within historical control range both sexes (0–6%/0–10% for M/F); no significant difference between controls and treated groups in incidence of specific tumours, total number animals with tumours, in the incidence of benign or malignant tumours or in the number of tumour-bearing animals; no effect on time-dependent occurrence of tumours. Dosing was considered adequate.
2-year dietary—oncogenicity rats	50 Wistar rats/sex/dose **Dose Levels**: 0, 100, 500, 2500, or 15 000 ppm (equal to 0/0, 4.6/6.0, 23.0/29.7, 116.1/155.6 and 768.8/1024.4 mg/kg bw/d for M/F).	**NOAEL**: 500 ppm (23.0/29.7 mg/kg bw/d for M/F) **LOAEL**: 2500 ppm (116.1/155.6 mg/kg bw/d for M/F)	2500 ppm: lower bw and bwg (F), increased thyroid wt (M) and diffuse hypertrophy and focal hyperplasia of follicular cells of thyroid (M/F). 15 000 ppm: all animals sacrificed at approx. 17 months due to excessive body-weight loss in females and increased mortality in males without further examinations. Thyroid follicular cell adenomas noted in 0/50, 0/50, 1/50 and 4/50 males at 0, 100, 500 and 2500 ppm, respectively and in 0/50, 1/50, 0/50 and 3/50 females at 0, 100, 500 and 2500 ppm, respectively; exceeded historical control range for males but not females (0–6%/0–10% for M/F); thyroid follicular cell carcinomas noted in 1/50 control males; no dose-related increase number of animals with tumours (benign or malignant) or in total number of primary neoplasms; no treatment-related effect on time-dependent occurrence of tumour bearing animals. Dosing was considered adequate.

STUDY	SPECIES, STRAIN AND DOSES	NOAEL & LOAEL mg/kg bw/day	TARGET ORGAN, SIGNIFICANT EFFECTS, COMMENTS
REPRODUCTION AND DEVELOPMENTAL TOXICITY—BAS 510 F TECHNICAL			
Multi-generation (1 litter/ generation)	25 Wistar (ChbbTHOM(SPF)) rats/sex/dose **Dose Levels**: 0, 100, 1000, or 10 000 ppm (equal to 0/0, 10.1/10.7, 101.2/106.8 and 1034.5/1062.0 mg/kg bw/d, respectively, for F_0M/F and 0/0, 12.3/12.5, 123.9/124.7 and 1295.4/1299.6 mg/kg bw/d, respectively, for F_1 M/F).	**PARENTAL**: **NOAEL**: Males: 1000 ppm (101.2 mg/kg bw/d) Females: 10 000 ppm (1062 mg/kg bw/d). **LOAEL**: Males: 10 000 ppm (1035 mg/kg bw/d) Females: not determined. **OFFSPRING**: **NOAEL**: 1000 ppm (101.2/106.8 mg/kg bw/d M/F). **LOAEL**: 10 000 ppm (1035/1062 mg/kg bw/d M/F) **REPRODUCTIVE**: **NOAEL**: 10 000 ppm (1035/1062 mg/kg bw/d for M/F). **LOAEL**: not determined	**PARENTAL**: 10 000 ppm: lower bw and bwg (F_1 males); minimal to moderate centrilobular hypertrophy and slight to marked/severe degeneration centrilobular hepatocytes (F_0/F_1 males). **OFFSPRING**: 10 000 ppm: lower bw and bwg (F_1/F_2 males and females). **REPRODUCTIVE**: No treatment-related findings. No indication that neonates are more sensitive than parental animals.
Developmental toxicity—rat	25 female Wistar rats/dose **Dose Levels**: 0, 100, 300, or 1000 mg/kg bw/d	**MATERNAL**: NOAEL: 1000 mg/kg bw/d. LOAEL: not determined. **DEVELOPMENTAL**: NOAEL: 1000 mg/kg bw/d LOAEL: not determined	**MATERNAL**: no treatment-related findings. **DEVELOPMENTAL**: no treatment-related findings. **TERATOGENICITY**: No evidence of any treatment-related irreversible structural changes at any dose level up to and including 1000 mg/kg bw/d (HDT); therefore, under the conditions of this study, BAS 510 F was not teratogenic. No increase in susceptibility of the fetus to in utero exposure.

STUDY	SPECIES, STRAIN AND DOSES	NOAEL & LOAEL mg/kg bw/day	TARGET ORGAN, SIGNIFICANT EFFECTS, COMMENTS
Developmental toxicity—rabbit	25 Himalayan rabbits/dose **Dose Levels**: 0, 100, 300, or 1000 mg/kg bw/d	**MATERNAL**: NOAEL: 300 mg/kg bw/d LOAEL: 1000 mg/kg bw/d	**MATERNAL**: 1000 mg/kg bw/d: lower bw/bwg; increased number of abortions (2 on GD 27 and 1 on GD 29) and/or early delivery (1 on GD 29). Prior to aborting and/or premature delivery, dams exhibited bw loss and lower food consumption.
		DEVELOPMENTAL: NOAEL: 300 mg/kg bw/d LOAEL: 1000 mg/kg bw/d	**DEVELOPMENTAL**: 1000 mg/kg bw/d: increased number of abortions (2 on GD 27 and 1 on GD 29) and/or early delivery (1 on GD 29). **TERATOGENICITY**: No evidence of any treatment-related irreversible structural changes; therefore, under the conditions of this study, BAS 510 F was not teratogenic. No increase in susceptibility of the fetus to in utero exposure

GENOTOXICITY—BAS 510 F TECHNICAL

STUDY	SPECIES AND STRAIN OR CELL TYPE	CONCENTRATIONS OR DOSES	RESULTS
Gene mutations in bacteria	*Salmonella typhimurium* strains TA 98, TA 100, TA 1535 or TA 1537; *E. Coli* WP2uvrA	**Initial assay**: 0, 22, 110, 550, 2750 or 5500 μg/plate; ± S9 metabolic activation **Confirmatory assay**: 0, 20, 500, 2500 or 5000 μg/plate; ± S9 metabolic activation	**Negative**
Gene mutations in mammalian cells in vitro	Chinese hamster ovary cells (HGPRT locus)	**Initial assay**: 0, 15.625, 31.225, 62.5, 125, 250 or 500 μg/plate ± S9 metabolic activation **Confirmatory assay**: 0, 10.24, 25.6, 64, 160, 400 or 1000 μg/plate ± S9 metabolic activation	**Negative**
Chromosome aberrations in vitro	Chinese hamster V79 cells	**Initial assay**: 0, 20, 100 or 500 μ/mL ± S9 metabolic activation **Confirmatory assay**: 0, 125, 250 or 500 μg/mL (+) S9 metabolic activation; 0, 31.25, 62.5, or 125 μg/mL (-) S9 metabolic activation	**Negative**

GENOTOXICITY—BAS 510 F TECHNICAL			
STUDY	**SPECIES AND STRAIN OR CELL TYPE**	**CONCENTRATIONS OR DOSES**	**RESULTS**
Unscheduled DNA synthesis in vitro	Primary rat hepatocytes (male Wistar rats)	**Initial assay**: 0, 5, 10, 50, 100, 250, 500, 750 or 1000 μg/mL; due to excess toxicity repeated at 0, 3.125, 62.5 or 125 μg/mL. **Confirmatory assay**: 0, 1.563, 3.125, 6.25, 12.5, 25 or 50 μg/mL	**Negative**
Micronucleus assay (in vivo)	5 Male and female NMRI mice/dose (bone marrow cells)	0, 500 1000 or 2000 mg/kg bw (2 i.p. injections 24 h apart; cells harvested 24 h after final injection)	**Negative**
SPECIAL STUDIES—BAS 510 F TECHNICAL			
Acute Neurotoxicity—rat	10 Wistar rats/sex/dose **Dose Level**: 0, 500, 1000 or 2000 mg/kg bw	**Systemic Toxicity**: **NOAEL**: 1000 mg/kg bw **LOAEL**: 2000 mg/kg bw **Neurotoxicity**: **NOAEL**: 2000 mg/kg bw **LOAEL**: not determined	**Systemic Toxicity**: 2000 mg/kg bw: slight increased incidence piloerection on day of dosing (day 0); not considered to be an indication of neurotoxicity. **Neurotoxicity**: No evidence of neurotoxicity in either sex up to and including 2000 mg/kg bw, the HDT.
Sub-chronic Neurotoxicity—rat	10 Wistar rats/sex/dose **Dose Level**: 0, 150, 1500 or 15 000 ppm (equal 0/0, 10.5/12.7, 103.1/124.5 and 1050.0/1272.5 mg/kg bw/d for M/F)	**Systemic Toxicity**: **NOAEL**: 15 000 ppm (1031/1272 mg/kg bw/d M/F). **LOAEL**: not determined **Neurotoxicity**: **NOAEL**: 15 000 ppm (1031/1272 mg/kg bw/d M/F). **LOAEL**: not determined	**Systemic Toxicity**: no adverse treatment-related systemic findings in either sex up to and including 15 000 ppm, the HTD. **Neurotoxicity**: no evidence of neurotoxicity in either sex up to and including 15 000 ppm, the HDT.

GENOTOXICITY—BAS 510 F TECHNICAL			
STUDY	**SPECIES AND STRAIN OR CELL TYPE**	**CONCENTRATIONS OR DOSES**	**RESULTS**
Developmental Neurotoxicity—rat	35 female Crl: WI (GLX/BRL/HAN) IGS BR (Wistar) rats/dose **Dose Levels**: 0, 100, 1000, or 10 000 ppm (equal to 0, 14, 147 and 1442 mg/kg bw/d)	**Maternal**: NOAEL: 10 000 ppm (1442 mg/kg bw/d) LOAEL: not determined **Offspring**: NOAEL: 100 ppm (14 mg/kg bw/d) LOAEL: 1000 ppm (147 mg/kg bw/d)	**Maternal**: no treatment-related systemic findings up to and including 10 000 ppm, the HTD. **Offspring:** 1000 ppm: lower bw (PND 4, approx. 8–9%) and bwg (PNDs 1–4, approx. 21%). 10 000 ppm: lower bw (males on PNDs 4–21, approx. 6–14% and females on PNDs 1–21, approx. 6–16%); lower bwg both sexes (PNDs 1–4 approx. 32%, PNDs 17–21 approx. 8–11% and PNDs 4–21 approx. 4–5%) No evidence of developmental neurotoxicity. There was quantitative evidence of increased susceptibility.
Hepatic Enzyme Induction—rat (non-guideline)	Male and female Wistar rats (5/sex/dose) **Dose Levels**: 0 or 15 000 ppm (approximately 0 and 1500 mg/kg bw/d) for 14 days	NOAEL/LOAEL not determined	15 000 ppm: increased liver wt (M/F); slight to extensive proliferation/accumulation SER in centrilobular hepatocytes with moderate glycogen depletion (M/F); increased CYP450 activity (M/F); no peroxisome proliferation (CYP450 4A); no increase EROD activity (CYP450 1A); 2× increase PROD activity (CYP450 2B6) in males considered secondary since not of magnitude expected relative to total CYP450; no increased glutathione concentration; increased lipid peroxidation in males (oxidative stress secondary to CYP450 induction); induction of CYP450; however, the subfamily not identified.
Hormone and Enzyme Induction—rat (non-guideline)	Male and female Wistar rats (5/sex/dose) **Dose Levels**: 0 or 15 000 ppm (approximately 0 and 957/1197 mg/kg bw/d for M/F) for 28 days	NOAEL/LOAEL not determined	15 000 ppm: increased liver wt (M/F); persistent decrease T3/T4 for males throughout study; slight decrease T3/T4 for females, although not consistent; persistent increase TSH activity (M/F), more pronounced in females; increased glucuronyltransferase activity (M/F).

GENOTOXICITY—BAS 510 F TECHNICAL			
STUDY	**SPECIES AND STRAIN OR CELL TYPE**	**CONCENTRATIONS OR DOSES**	**RESULTS**
4-week reversibility—rat (non-guideline)	15 male Wistar rats/dose (5/dose sacrificed following 0, 4 or 13-wk recovery) **Dose Levels**: 0, 100, 2500 or 15 000 ppm (equivalent to 0, 7.7, 190.3 and 1137.4 mg/kg bw/d)	**NOAEL**: 100 ppm 7.7 mg/kg bw/d) **LOAEL**: 2500 ppm (190 mg/kg bw/d)	≥2500 ppm: increased serum TSH levels; increased liver/thyroid wt; centrilobular hepatocellular hypertrophy and fatty changes in the portal region of liver; hypertrophy follicular epithelial cells and diffuse follicular hyperplasia in thyroid. 15 000 ppm: enlarged liver. Absence of treatment-related findings following 4- and 13-wk recovery period suggest findings noted at 2500 and 15 000 ppm are reversible upon cessation of treatment.
Compound-induced mortality: There was no significant increased incidence of treatment-related mortalities in any short-term, long-term or special studies.			
Recommended ARfD: An acute reference dose (ARfD) was not established since BAS 510 F was considered unlikely to present an acute hazard. There were no significant treatment-related findings in the acute, short-term, 2-generation reproduction or developmental toxicity studies to indicate a concern in acute dietary risk assessment.			
Recommended ADI: 14 mg/kg bw/d from the developmental neurotoxicity study based on lower pup body weight on PND 4 and lower pup body-weight gain on PND 1–4 at the LOAEL (147 mg/kg bw/d, the next highest dose). Safety Factor = 100× to account for intra- and inter-species variations. No additional safety factor required. ADI = NOAEL/SF = 14 mg/kg bw/d/100 = 0.14 mg/kg bw/d.			

Appendix III Residues

Table 1 Summary of food residue studies

PARAMETER		PERTINENT INFORMATION				
Boscalid		**Boscalid**				
Crop	**Formulation/ type**	**Method/Timing**	**Rate g a.i./ha**	**Number/ season**	**Maximum Rate g a.i./ha**	**PHI (days)**
Canola	wettable granule	Apply at 20–50% flowering and again 7–14 days later if disease persists or weather favours disease. Use high rate for extended protection and max yield.	245–294	2	592	21
Dry beans, faba or broad beans (dry)	wettable granule	Apply at 20–50% flowering and again 7–14 days later if disease persists or weather favours disease. Use high rate for extended protection and max yield.	392–539	2	1079	21
Chickpea and lentil	wettable granule	Apply at beginning of flowering and again 7–14 days later if disease persists or weather favours disease.	294	2	592	21
Succulent bean	wettable granule	Apply at 20–50% flowering and again 7–14 days later if disease persists or weather favours disease. Use high rate for extended protection and max yield.	392–539	2	1079	7
Head lettuce, leaf lettuce	wettable granule	Direct seeded lettuce—apply immediately after thinning (within 2 days) and again 10–20 days later if conditions continue to favour disease. Transplanted lettuce—apply 7–10 days after transplanting and again 10–20 days later. Use high rate when disease pressure is high. Ensure coverage of lower portion of plant and surrounding soil surface.	200	2	400	14
Fruiting vegetables	wettable granule	Apply prior to disease development and at 7–10 day intervals. Use high rate and shorter interval when disease pressure is high.	220	5	1100	1

PARAMETER		PERTINENT INFORMATION				
Boscalid		**Boscalid**				
Crop	**Formulation/ type**	**Method/Timing**	**Rate g a.i./ha**	**Number/ season**	**Maximum Rate g a.i./ha**	**PHI (days)**
Potato	wettable granule	Apply prior to disease development and at 14 day intervals if conditions continue to favour disease. Do not apply more than 1.44 kg/ha per season	220	4	880	30
Bulb vegetable	wettable granule	Apply prior to disease development and at 7–14 day intervals. Use shorter interval when disease pressure is high.	330	6	1980	7
Carrots	wettable granule	Apply prior to disease development and at 7–14 day intervals. Use shorter interval when disease pressure is high.	220	5	110	0
Stone fruit	wettable granule	Apply from pink bud or prior to disease development and at 7–14 day intervals. use shorter interval when disease pressure is high.	260	5	1300	0
Small berries	wettable granule	Apply prior to disease development and at 7–14 day intervals. Use shorter interval when disease pressure is high.	390	4	1560	0
Grape	wettable granule	Apply from bud break and at 10–14 day intervals.	224	5	1120	14
Strawberries	wettable granule	Apply prior to disease development and at 7–14 day intervals. Use shorter interval when disease pressure is high.	390	5	1950	0
Use on the U.S. label only (US BAS 510 02 F Crop Fungicide)						
Tree nuts	wettable granule	At pink bud or prior to disease development	0.27	4	1075	14
Pistachio	wettable granule	Prior to disease development	0.27	4	1075	14
Peanuts	wettable granule	Disease dependent	0.52	3	1540	14

LABEL RESTRICTIONS		
PHYSICOCHEMICAL PROPERTIES	**Substance**	**Value**
Water solubility at 20°C	pure active ingredient (PAI)	4.64 mg/L
Solvent solubility at 20°C	PAI	acetone (16–20 g/100 mL); acetonitrile (4–5 g/100 mL); methanol (4–5 g/100mL); ethylacetate (6.7–8 g/100 mL); dichloromethane (20–25g/100 mL); toluene (2–2.5 g/100mL); 1-octanol (<1g/100mL).
Octanol–water partition coefficient (K_{ow})	PAI at 21°C	log K_{ow} is 2.96 (K_{ow} of 915). Because the compound does not dissociate, the value of K_{ow} is not pH dependent.
pK_a	N/A	Does not dissociate
Vapour pressure	PAI	7×10^{-9} hPa (PAI at 20°C); 2×10^{-8} hPa (PAI at 25°C)
Relative density	TGAI PAI	1.394 g/cm^3 1.381 g/cm^3
NATURE OF THE RESIDUE—Animals		
Radiolabelling positions	[^{14}C]BAS 510 F, uniformly labelled on the phenyl rings (diphenyl label) or labeled at the 3-position of the pyridine ring.	
Proposed Metabolic Pathway	BAS 510 F is metabolized in goats and hens through hydroxylation of the diphenyl portion to form M510F01. M510F01 then undergoes glucuronidation to form M510F02. Further hydroxy and thiol substitutions in the diphenyl portion occur. In addition, the chlorine atom on the pyridine ring is substituted by thiol groups from endogenous sources i.e., from biomolecules.	
Residue of Concern (ROC)	The combined residues of BAS 510 F and its hydroxy metabolite, free (M510F01) and bound (M510F02), all expressed in parent equivalents.	
NATURE OF THE RESIDUE—Plants		
Radiolabelling positions	[^{14}C]BAS 510 F, uniformly labeled on the phenyl rings (diphenyl label) or labeled at the 3-position of the pyridine ring.	
Proposed Metabolic Pathway	In primary crop, essentially no metabolism was observed. Limited hydroxylation and conjugation as well as cleavage of the molecule (but not of the ring structures) was observed as demonstrated by the presence of the cleavage products 2-chloronicotinic acid and chlorophenylaminobenzene.	
ROC	Parent only	

RESIDUE ANALYTICAL METHOD	*PLANT*	*ANIMAL*
Method ID	Data Collection Method: D9908 Enforcement Method: D0008	Data Collection Method: D471/0 and 476/0 Enforcement Method: DFG S19
Analytes	Parent	The combined residues of BAS 510 F and its hydroxy metabolite, free (M510F01) and bound (M510F02), all expressed in parent equivalents.
Instrument/Detector	**Method D9908: LC/MS/MS**: The LC system utilizes an Intersil Phenyl 5 m® column (C_{18}) and an isocratic mobile phase of methanol:4 mM ammonium formate:0.1% formic acid (80:19.9:0.1, v:v:v). MS/MS detection using the positive ionization mode monitors ion transitions from m/z 343 to 307. Quantitation is obtained using an external calibration curve of BAS 510 F standards. **Method D0008: GC/MS (SIM):** Residues are redissolved with 0.01% polyethylene glycol (M_n ca. 400) in toluene and analysed using GC/MS with selected ion monitoring (SIM). The method lists monitoring ions of *m/z* 342, 142 or 140, and notes that any ion can be used for quantitation based on the cleanness of the chromatograms. Quantitation is performed using an external calibration curve of BAS 510 F standards.	**Method D471/0: LC/MS/MS** The HPLC system utilizes a High Purity Elite C18 column and a gradient mobile phase of water, methanol and formic acid. MS/MS detection using the positive ionization mode monitors ion transitions from m/z 359 to 140 and 323 for BAS 510 F and m/z 343 to 140 and 307 for M510F01. Quantitation is conducted using an external calibration curve of BAS 510 F and M510F01 standards. **Method 476/0: GC/MS (SIM)** Method 476/0 was developed to determine non-extractable residues of BAS 510 F in liver and milk. The method is a common moiety method based on the quantification of the metabolite M510F53. Microwave hydrolysis experiments revealed that this conjugation modified the reactivity of the whole molecule, allowing the amide bond to be cleaved during microwave treatment. If the microwave hydrolysis was conducted using acetic acid, metabolite M510F53 could be generated. The hydrolysis of the amide bond was not observed during microwave treatment of the parent or its metabolite M510F01. Therefore, M510F53 is used as a marker analyte for bound residues of BAS 510 F in liver. The microwave hydrolysis techniques were also applied to milk samples in the goat metabolism study, theoretically releasing conjugated residues of BAS 510 F. The residues are dissolved in ACN for GC/MS analysis. The MS detector uses selected ion monitoring (SIM); ion m/z 167 was detected for M510F53. For method validation, samples of milk and cow liver hydrolysates were fortified with M510F53 in acetonitrile (ACN) after the microwave hydrolysis step. Quantitation is obtained using an external calibration curve of M510F53 standards.

RESIDUE ANALYTICAL METHOD	*PLANT*	*ANIMAL*
		Method DFG S19: GC/ECD The GC system uses a Varian Chrompack CP Sil 8 column and electron capture detection. Quantitation is obtained using an external calibration curve of standards of BAS 510 F and the acetyl derivative of M510F01. The M510F01 acetyl derivative standards are calculated as BAS 510 F equivalents when determining the calibration curve; thus, residues of M510F01 are reported as BAS 510 F equivalents.
Standardization method	An external bracketing standard of BAS 510 is used in the analysis of multiple matrices.	External bracketing standards of BAS 510, BAS 510 F01 and BAS 510 F02 are used in the analysis of multiple matrices.
Stability of primary and/or secondary standard solutions	Standard solutions (acetonitrile, solvent) of BAS 510 F and various of its metabolites (M510F01, M510F49, M510F51 and M510F53) were tested and found to remain stable during 62 days of storage (duration of study), either refrigerated in the dark or at room temperature with daylight exposure.	
Retention times	**Method D9908**: 2:21min **Method D0008**: 3:30 min	**Method D471/0:** BAS 510: 3 min, BAS 510 F01: 7–8 min **Method D476/0:** BAS 510 determined as BAS 510 F53 (after microwave extraction): 9.0 min. **Method DFG S19**: For BAS 510, 10.1 min. For BAS 510 F01, 13.6 min
Limit of detection (LOD) *Limit of quantitation (LOQ)*	**Method D9908**: LOQ = 0.05 LOD, 5 pg/μL **Method D0008**: LOQ = 0.05 LOD, 2 pg/μL	**Method D471/0:** For both parent and BAS 510F01, 0.01 ppm in eggs, milk and cream and 0.025 ppm in meat, fat, kidney and liver. The LOD was not determined. **Method 476/0:** BAS 510 determined as BAS 510 F53 (after microwave extraction): 0.05 and 0.01 ppm for liver and milk respectively. **Method DFG S19**: For both parent and hydroxymetabolite expressed as parent equivalents: For milk, LOQ = 0.1 ppm, LOD = 0.002 ppm. For meat, fat and eggs, LOQ = 0.025 ppm, LOD = 0.005 ppm
Repeatability/Precision	**Method D9908**: Acceptable recoveries were obtained in multiple matrices over a wide range of spiking levels. **Method D0008**: Acceptable recoveries were obtained in multiple matrices over a wide range of spiking levels.	**Method D471/0:** Acceptable recoveries were obtained in multiple matrices over a wide range of spiking levels. **Method 476/0:** Acceptable recoveries were obtained in multiple matrices over a wide range of spiking levels. **Method DFG S19**. Acceptable recoveries were obtained in multiple matrices over a wide range of spiking levels for both parent and the hydroxy metabolite.

RESIDUE ANALYTICAL METHOD	*PLANT*	*ANIMAL*
Reproducibility	An ILV of GC/MS enforcement **Method D0008**, was conducted to verify the reliability of the method for the determination of BAS 510 residues in/on canola and tomato. The recovery values obtained with the initial trial indicate that the method D0008 is reliable at the method LOQ (0.05 ppm) and higher (70× LOQ).	An ILV of GC/MS enforcement **Method DFG S19**, was conducted to verify the reliability of the method for the determination of BAS 510 residues in/on multiple animal commodities. The recovery values obtained for both parent and the metabolite BAS 510-01 indicate that the method was reproducible at the LOQ and at 10 × LOQ.
Linearity	**Method D9908**: Demonstrated over the range of 0.1–10 pg/μL (r = 0.998). **Method D0008**: Demonstrated over the range of 2–20 ng/mL r = 0.993).	**Method D471/0:** For BAS 510 linearity was demonstrated over the range of 0.025–0.25 ppm with correlation coefficient of >0.99. For BAS 510 F01, Linearity was demonstrated over the range of 0.025–0.25 ppm with correlations coefficients (r) of >0.99 **Method 476/0:** For BAS 510 determined as BAS 510 F53 (after microwave extraction) linearity was demonstrated over the range of 0.02–0.2 ppm with correlations coefficients of >0.99 in both liver and milk. **Method DFG S19**: Demonstrated for both analysts in multiple matrices in the range of 0.01–0.25 ppm (as appropriate) correlations coefficients (r) were all > 0.999.
Specificity	**Method D9908**: Control interferences in multiple matrices were <0.01 ppm. **Method D0008**: Control interferences in multiple matrices were <0.01 ppm.	**Method D471/0:** Control interferences in multiple matrices were <0.01 ppm. **Method 476/0:** Control interferences in multiple matrices were <0.01 ppm. **Method DFG S19:** Control interferences in multiple matrices were <0.01 ppm.
MULTIRESIDUE METHOD	Residues of BAS 510 F and its metabolite M510F01 were not adequately recovered using the multiresidue methods. Protocol A was not applicable. Protocol B was not applicable for BAS 510 F and yielded inconsistent recoveries of M510F01. Residues of BAS 510 F and its hydroxy metabolite M510F01 had good responses with GC/ECD on a DB-1 column under Protocol C. Neither analyte was recovered at 30% using Protocols D, E and F.	

STORAGE STABILITY DATA	Submitted freezer storage stability data indicate that residues of BAS 510 F are stable in diverse representative **crop matrices** (sugar beet root, cabbage, canola seed, pea, peach, and wheat grain, forage and straw) for up to approximately 1 year (ongoing study; further sampling planned at 18 and 24 months). These data support the freezer storage interval (from collection to analysis) of samples in the crop field trial, field accumulation and processing studies. BAS 510 F residues have been shown to be stable in peanut oil and meal stored frozen for up to 45 days (duration of study). These data support the freezer storage interval (from collection to analysis) of samples in the peanut processing study and other similar matrices. Freezer storage stability data are required for grape juice and tomato paste and tomato puree as a **condition of registration**. Submitted freezer storage stability data for **cattle and poultry** matrices indicate that residues of BAS 510 F and its hydroxy metabolite M510F01 are stable for up to 5.5 months (duration of study) in cow milk, liver and muscle (only matrices tested) and 2.6 months (duration of study) in eggs (only poultry matrix tested). These data support the freezer storage interval (from collection to analysis) of samples in the cattle and poultry feeding studies.

CROP FIELD TRIALS	
Background	Residues of BAS 510 are persistent in the environment with a half-life calculated to be greater than 500 days. These residues are bioavailable and accumulate in measurable amounts in rotational crops (see section 4.1.1 and below). The occurrence of residues in rotational crops is of regulatory concern for both the establishment of appropriate MRLs and from a human health risk perspective. These concerns can be addressed in one of th[illegible]ays: imposing an extended plant back interval (1–2 years); establishing M[illegible] based on a full complement of residue trials carried out with direct application to the crop (**primary use**); or establishing MRLs based on a full set of trials where the exposure to the food crop is indirect (**rotated crop**). BASF implemented a residue program that illustrated the potential for residues on virtually all commercially grown crops. This program includes a mixture of trials carried out with the direct application to the crop (**primary use**) as well as a comprehensive program of residue trials where the resulting residues represent those expected in rotated crops (**rotational crops**). As a result of the timelines established in the Management of Submission Policy, the PMRA does not review residue data that is not germaine to a specific submission under consideration. However, because measurable residues were found in rotated crops and as a consequence of the strategy employed by BASF (outlined above), the review of additional crop residue data not directly associated with the crops on the proposed label was undertaken. It is important to note that the review of this additional residue data was undertaken solely for the purpose of addressing the residues in rotated crops. The additional residue trials identified are required to support the MRL due to the transfer from the soil to the plant, and are not intended to support the domestic use of this pesticide on these additional crops. In the eventuality that the registrant wishes to use the residue data to support a domestic use on these additional crops, the acceptability of the residue data will be assessed against the supported lowest effective rate. The results from the supervised residue trials where the crop was treated directly (**primary use**) are presented in ascending crop group (Crop Group 1–20) order below. The petitioned use for crops that do not fit in the established crop groups are listed alphabetically after. The residue data that directly supports a use on the proposed Canadian label is identified in the section where the results of the residue trials are discussed. The data that do not support a use on the proposed Canadian label, but are used instead to cover potential residues in rotated crops, are also identified in the appropriate section. When data used to identify the residues resulting from a primary use are extended to cover residues in rotational crops, a rationale for these extensions is presented. Results from supervised field trials where the active ingredient is not applied directly to the crops (**rotated crop**) are presented in the rotational crop section.

Primary use on: Root vegetables, except sugar beet (Crop Subgroup 1B)	Carrots are on the proposed Canadian label. The trials were carried out at 1.04× gap and a PHI of 0 days. Eight **carrot** crop field trials, including a decline trial, were conducted. Based on the number of trials submitted, the proposed use pattern and the results obtained from these trials, no additional carrot residue trials are required for carrot or for carrot as a representative crop of Crop Subgroup 1B. Mature carrots (tops removed) were collected and stored frozen for ≤6.9 months prior to analysis. Acceptable freezer storage stability data are available. LC/MS/MS method D9908 was validated and used for quantitation of the residues in this matrix. Quantifiable residues of BAS 510 in carrot root were reported in 7 of 8 trials. Residues ranged from <0.05 to 0.38 ppm. The study is acceptable to fulfill field trial data requirements for carrot and, in conjunction with the residue data on radish, for consideration of an MRL on Crop Subgroup 1B. **Radishes** are not on the proposed Canadian label, however radish is one of the representative crops of Crop Subgroup 1B. Five **radish** residue decline trials were conducted. The radish roots and tops collected in the five trials were frozen for ≤6.2 months prior to analysis. Acceptable freezer storage stability data are available. LC/MS/MS method D9908 was validated and used for quantitation of the residues in this matrix. Quantifiable residues of BAS 510 were reported in all treated samples at 0-day PHI. Residues ranged from 0.06 to 0.61 ppm in radish root and from 20.7 to 61.4 ppm in radish tops. The study is not acceptable to fulfill field trial data requirements for radish. The number and location of trials do not meet the requirements outlined in DIR98-02 for radish alone or for radish as a representative crop of Crop Subgroup 1B. Though the zonal requirements for Canada were not met, sufficient data is available to support the temporary domestic registration for Crop Group 1B pending two additional radish trials carried out in zone 5B. It should be noted that these trials are needed to support not only the use of this chemical on this crop group but also to support the residue levels resulting in rotated crops. **Primary and rotational residues in Crop Subgroups 1A & 1B: rationale in support of the MRL.** As carrots are the only crop on the current label, an MRL is needed to cover rotational residues/secondary residues in the rest of the "root vegetables (except sugarbeet)" in Crop Subgroup 1B and, separately, for beet root. BASF has indicated their intent to extend the current Canadian label to include the crops in subgroup 1B as a direct use or target crop use with the exception of sugar beet, garden beet, turnip and radish where direct application is not intended (i.e., a direct use on 1B crops whose tops are consumed will be excluded) and will be prohibited on the labels. Pending the submission and review of additional residue data in radish (as outlined above) sufficient conventional crop field trial data is available for carrot and will be available for radish. Based on the information provided and in anticipation of the additional residue data the current regulatory recommendation is direct use (target crop) MRL of 0.7 ppm for "root vegetable (except sugarbeet) Crop Subgroup 1B". A PBI of 14 days is needed in order to cover potential rotational residues/secondary residues in garden beet, radish and turnip.

Primary use on: The tuberous and corm vegetables (Crop Subgroup 1C)	Potatoes are on the proposed Canadian label. The residue trials submitted were carried out at the proposed Canadian rate (1.17× gap) and a PHI of 30 days. Sixteen field trials, including two decline trials, were conducted on potato, the sole representative crop of the tuberous and corm vegetable subgroup, at the proposed use pattern. An additional test plot in one trial was treated at a 5× rate to provide higher residues for processing. The samples of potato tubers collected in the trials mentioned above were stored frozen for 4.5 months prior to analysis. Acceptable freezer storage stability data are available. LC/MS/MS method D9908 was validated and used for quantitation of the residues in this matrix. Non-quantifiable residues (<0.05 ppm) of BAS 510 F were reported in all potato tubers, including those treated at the 5× rate, so a processing study was not required. An MRL of 0.05 ppm for the tuberous and corm vegetable Crop Subgroup (1C) is therefore recommended. However, as a condition of registration additional residue trials are required to satisfy Canadian registration requirements. These requirements are: four additional trials carried out in zones 1 (one trial), 1A (two trials) and 14 (one trial). These are needed to support a use in Canada (to satisfy the requirements of DIR98-02) on potato and for the MRL on Crop Subgroup 1-C.
Rotational residues on the leaves of root and tuber vegetables (Crop Group 2)	There is no direct application to these commodities on the proposed label. Due to the soil persistence (and subsequent uptake of the residue by rotational crops), an MRL of 1.0 ppm for Crop Group 2 (in conjunction with a 14-day PBI) is needed. The only supporting data which demonstrated the potential residues in these matrices is provided by translation of the rotational crop residue data for radish tops (0.25–0.82 ppm, 14-day PBI) reported in the limited field accumulation study. Another set of field accumulation trials must be conducted to provide confirmatory data on beet tops (sugar or garden) and turnip tops (2 sites for each). The location of these trials is left to the discretion of the registrant, however they must be representative of the primary growing regions in Canada. Provided these data show that the 1.0 ppm MRL is sufficient to cover residues for the commodities in Crop Group 2, further studies would not be required if no direct application is proposed to these food commodities. If the results from these two additional trials indicate that the proposed MRL of 1 ppm is insufficient, a full set of residue trials will be required. Should the registrant wish to expand the use of BAS 510 to include a direct application to these commodities, additional residue trials will be needed since residues would exceed the proposed MRL of 1.0 ppm.

Primary use on: Bulb Vegetables (Crop Group 3)	For both green onions and dry bulb onions, trials were carried out at 1.03× the rate of the proposed Canadian label and the crop harvested 7 days after the last application. Nine field trials, including a decline trial, were conducted on green onions (3 trials) and dry bulb onions (6 trials), the representative crops of the bulb vegetables Crop Group, using the proposed use pattern. Samples were stored frozen for 6.1 months prior to analysis. Acceptable freezer storage stability data are available. LC/MS/MS method D9908 was validated and used for quantitation of the residue in these matrices. Quantifiable residues of BAS 510 F were reported in all trials. Residues ranged from <0.05 to 1.0 ppm in dry bulb onions and from 1.0 to 2.9 ppm (HAFT = 2.7 ppm) in green onions. The data support an MRL of 3.0 ppm for the bulb vegetables Crop Group (CG-3). However, as a condition of registration, a total of four additional trials in dry bulb onions (two trials carried out in zone 5 and two trials carried out in zone 5B) and two additional trials in green onions (one trial in each of zone 5 and 5B) will be needed to support the use of this chemical on the crops of Crop Group 3 and to support the MRL.

Primary use on: Leafy vegetables (Crop Group 4)	Lettuce (head and leaf) is on the proposed Canadian label. The residue trials were carried out at 2× gap with a PHI of 14 days. Sixteen crop field trials, including two decline trials, were conducted on head lettuce (8) and leaf lettuce (8) at the proposed use pattern. The data presented can only be used to support a temporary registration in lettuce (both head and leaf) and cannot be extended to any other crop in the leafy vegetable group. Samples of head (± wrapper leaves) and leaf lettuce collected in the sixteen trials submitted were stored frozen for 6.3 months prior to analysis. Acceptable storage stability data are available. LC/MS/MS method D9908 was validated and used for quantitation of the residues in lettuce. Quantifiable residues of BAS 510 F were reported in all but one trial. Residues ranged from <0.05 to 0.95 ppm in head lettuce (without wrapper leaves), from 0.08 to 6.2 ppm (HAFT = 5.4 ppm) in head lettuce (with wrapper leaves) and from 0.36 to 10.4 ppm in leaf lettuce. Little, if any, of the submitted lettuce trials were carried out in common zones between the U.S. and Canada. As there is no zonal representation and as the trials were carried out at 2 times the label rate, the PMRA will consider a domestic registration for the use of BAS 510 on lettuce only if the registrant commits to one of the following options: Option 1, a full set of residue trials (five trials) as specified in DIR98-02 or, Option 2, the registrant can provide two trials in each of zones 5 and 5B (for a total of 4 trials). For both options, the trials must be carried out at the proposed Canadian label rate. **Primary and rotational residues on Crop Group 4: rationale in support of the MRL** The petitioner has requested that an MRL, not for lettuce per se, but for the entire leafy vegetables crop group be promulgated. As no residue data were submitted for celery or spinach, which, with head and leaf lettuce, are the representative crops of the crop group, an MRL to cover the residues of BAS 510 in all of the crops in leafy vegetables crop group based solely on residue data from lettuce cannot be supported. The data does support an MRL on lettuce. Due to the differences observed in head and leaf lettuce, MRLs of 6.5 ppm and 11.0 ppm for head and leaf lettuce respectively are recommended. In addition, a rotational residues/secondary residues MRL on "leafy vegetables (except lettuce)" at 1.0 ppm (in conjunction with a 14-day PBI) is recommended. The supporting data for this rotational residues/secondary residues MRL is provided by translation of the rotational crop residue data for radish tops (0.25–0.82 ppm, 14-day PBI) reported in the limited field accumulation study. We will allow this MRL but request, as a condition of registration, that another set of limited field accumulation trials (2 sites) be conducted to provide data on spinach and celery. These studies should be carried out in zones typical of Canadian conditions. Provided those data show the 1.0 ppm level expected in rotational crops of "leafy vegetables (except lettuce)" is not exceeded, further studies would not be required. Alternatively, the petitioner may provide target crop field trial data on spinach and celery, in accordance with DIR98-02 requirements and seek a direct use with a supporting MRL on all of Crop Group 4.

Primary use on: Head and Stem Brassica (Crop Subgroup 5A)	The crops in Crop Group 5 (A&B) are not on the proposed Canadian label. Twelve residue decline crop field trials were conducted on broccoli (6) and cabbage ± wrapper leaves (6), the representative crops of the head and stem Brassica subgroup (Crop Subgroup 5A). Samples collected from the trials carried out in the U.S., were stored frozen for 5.6 months prior to analysis. Acceptable freezer storage stability data are available. LC/MS/MS method D9908 was validated and used for quantitation of the residue in these matrices. At a PHI of 0-days, residues of BAS 510 ranged from 0.72 to 2.73 ppm in broccoli and from 0.60 to 2.82 ppm in cabbage (with wrapper leaves). Due to the lack of representative data from zones applicable to Canada, the PMRA will not support the domestic registration of BAS 510 on the Head and Stem Brassica (Crop Subgroup 5A) based on the information provided. The USEPA has determined that the data support a target crop (direct use) tolerance of 3.0 ppm on Crop Subgroup 5A. An MRL of 3.0 ppm will be recommended by the PMRA. This MRL will cover residues in imported crops from this subcrop group and potential residues in these crops when they are planted as rotational crops.
Primary use on: Leafy Brassica Greens (Crop Subgroup 5B)	Five residue decline crop field trials were conducted on mustard greens, which is the representative crop of the leafy Brassica greens subgroup (Crop Subgroup 5B). Samples collected from the five trials submitted were frozen and stored 6.6 months prior to analysis. Acceptable freezer storage stability data are available. LC/MS/MS method D9908 was validated and used for the quantitation of the residues in these samples. At a PHI of 14 days, residues of BAS 510 ranged from 0.43 to 15.4 ppm in mustard greens. The currently available data support a target crop (direct use) MRL of 18.0 ppm on Crop Subgroup 5B. Though not specified in DIR98-02, mustard greens are grown in Canada. Based on guideline requirements, a domestic registration would require a total of three trials (2 in zone 5 and 1 in zone 12). Based on the zonal distribution of the data submitted, the PMRA will require one additional trial in zone 12. The MRL proposed will cover both primary (from imported U.S. commodities) and rotational residues/secondary residues on leafy Brassica greens (Crop Subgroup 5B).

Primary use on: Legume Vegetables—Crop Group 6	Beans are on the proposed Canadian label. For succulent beans, trials were carried out at 1.05× gap and a PHI of 7 days. For dry beans, trials were carried out at 1.04× gap and a PHI of 21 days. Peas are not on the current Canadian label. Twenty-seven field trials, including three decline trials, were conducted on snap bean (10), lima bean (7), and dried shelled bean (10), the three representative crops of the bean portion of the legume vegetables crop group, using the proposed use pattern. The number and location of trials meet the residue requirements (DIR98-02) for the beans part of Crop Group 6. Mature samples were collected and were stored frozen for 8.1 months prior to analysis. Acceptable freezer storage stability data are available. LC/MS/MS method D9908 was validated and used for the quantitation of the residues. Quantifiable residues of BAS 510 F were reported in 21 of 27 trials. Residues ranged from 0.10 to 1.16 ppm in snap bean, from <0.05 to 0.54 ppm in lima bean and from <0.05 to 2.35 ppm in dried shelled bean. The study is acceptable and fulfills the field trial data requirements (DIR98-02) for succulent edible-podded bean, succulent shelled bean and dried shelled bean as part of Crop Group 6. Twenty field trials were conducted on succulent edible-podded pea (3), succulent shelled pea (8) and dried shelled pea (9), the three representative crops of the pea portion of the legume vegetables crop group, using the proposed use pattern. The number and location of trials meet the requirements set out in DIR98-02 for peas as part of Crop Group 6. Mature samples were collected and frozen stored for 7.4 months prior to analysis. Acceptable supporting frozen storage stability data are available. LC/MS/MS method D9908 was validated and used for the quantitation of residues in these matrices. Quantifiable residues of BAS 510 F were reported in 18 of 20 trials. Residues ranged from 0.60 to 1.53 ppm in succulent edible-podded pea, from <0.05 to 0.39 ppm in succulent shelled pea and from <0.05 to 0.46 ppm in dried shelled pea. The study is acceptable and fulfills the field trial data requirements (as set out in DIR98-02) for succulent edible-podded pea, succulent shelled pea and dried shelled pea as part of Crop Group 6. **Primary and rotational residues in Crop group 6 (except soybean): Rationale in support of the MRL** BASF intends to propose a direct use on the edible pea portion of Crop Group 6 with the exception of those pea varieties which may be used as animal feed (soybean, cowpea, field pea and lupin). Since sufficient crop field trial data for beans and edible peas has been submitted, the appropriate regulatory recommendation is now a target crop MRL of 1.6 ppm will be recommended for sub-Crop Group 6A; the edible-podded legume vegetable. An MRL of 0.6 ppm will be recommended to cover the crops in Crop Subgroup 6B; the succulent shelled pea and bean and an MRL of 2.5 ppm will be recommended to cover the residues in the crops of Crop Subgroup 6C the dried shelled pea and bean, excluding soybean, cowpea, field pea and lupin. An MRL (rotational residues/secondary residues) of 0.1 ppm for the seed of soybean, cowpea, field pea and lupin (in conjunction with a 14-day PBI) will be needed (see section on rotated crops below).

Direct use on: Fruiting Vegetables (Crop Group 8)	The crops of the fruiting vegetable group are on the proposed Canadian label. For tomato, the trials were carried out at 2× gap and a PHI of 0 days. For bell peppers, the trials were carried out at 1.67× gap and a PHI of 0 days. For chili peppers, the residue trials were carried out at 1.67× gap and a PHI of 0 days. Twenty-one field trials, including one decline trial, were conducted on tomato (12), bell pepper (6) and chili pepper (3), the three representative crops of the fruiting vegetables crop group. The samples were stored frozen 5.3 months prior to analysis. Acceptable freezer storage stability data are available. LC/MS/MS method D9908 was validated and used for the quantitation of the residues. Quantifiable residues of BAS 510 F were reported in all but one trial. Residues ranged from <0.05 to 0.99 ppm in tomato, <0.05–0.34 ppm in bell pepper and 0.13–0.96 ppm in chili pepper. As the zonal distribution of the submitted trials does not meet the PMRA's requirements (DIR98-02) and as these trials were carried out at 2× the label rate, an additional seven trials in tomato (6 trials carried out in zone 5 and one in zone 5B) and three trials in peppers (two carried out in zone 5 and one trial in zone 5B) are required to support domestic registration in Canada. All of these trials must be carried out at the accepted label rate. Pending the submission and review of the additional residue studies, an MRL of 1.0 ppm for the fruiting vegetables crop group (CG-8) is recommended.

Primary use on: Cucurbit Vegetables (Crop Group 9)	The crops in the cucurbit crop group are not on the proposed Canadian label. Eighteen field trials were conducted on cantaloupe (6), cucumber (6) and summer squash (6), the three representative crops of the cucurbit vegetables (Crop Group 9). Samples from the submitted trials were stored frozen 4.0 months prior to analysis. Acceptable freezer storage stability data are available. LC/MS/MS method D9908 was validated and used for the quantitation of the residues in these trials. Quantifiable residues of BAS 510 F were reported in all trials. Residues ranged from 0.22 to 1.48 ppm in cantaloupe, <0.05–0.16 ppm in cucumber and 0.10–1.08 ppm in summer squash. Due to the range of residues observed (>5×) in these trials, a crop group MRL is not appropriate. Though not on the current Canadian label, two additional residue trials (one trial in each of zones 5 and 5B) carried out in muskmelons, one additional trial carried out in zone 5B on cucumbers and two additional residue trials (one additional trial in each of zones 5 and 5B) carried out in squash are needed to support the registration of BAS 510 on any crop in Crop Group 9 and to support the recommended MRL. **Rationale in support of the MRL(s) on the crops of the Cucurbit Crop Group (9)** The maximum residue in cucumbers (0.16 ppm) is >5× lower than that in the other representative crops, cantaloupe (1.48 ppm) and summer squash (1.08 ppm), treated by the same use pattern. Thus, an MRL is not appropriate for the entire cucurbit vegetables crop group. Also, since the field trials submitted on cucurbits were conventional crop field trials, a rotational residues/secondary residues MRL is not appropriate. The data do support a target crop (direct use) MRL of 1.7 ppm for the "cucurbit vegetables (Crop Group 9), excluding cucumber" and an individual target crop MRL of 0.20 ppm on cucumber. Two additional residue trials (one trials in each of zones 5 and 5B) carried out in muskmelons, one additional trial carried out in zone 5B on cucumbers and the two additional residue trials (one additional trial in each of zones 5 and 5B) carried out in squash are required. The adequacy of the MRLs should be revisited upon receipt/review of the additional trials to be submitted.
Primary use on: Stone Fruit (Crop Group 12)	The crops of the stone fruit group are on the proposed Canadian label. The residue trials were carried out at 1× gap and a PHI of 0 days. Twenty-one field trials, including two decline trials, were conducted on cherry, tart and sweet (6), peach (9) and plum, fresh prune (6), the three representative crops of the stone fruit crop group, using the proposed use pattern. An additional field trial on plums was conducted at a 5× rate to generate higher residues for processing. Samples generated in the submitted studies were stored frozen for 4.3 months prior to analysis. Frozen storage stability was demonstrated for this period of time. LC/MS/MS method D9908 was validated and used for quantitation of the residues. Quantifiable residues of BAS 510 F were reported in all samples. Residues ranged from 0.64 to 1.64 ppm (HAFT = 1.53 ppm) in cherry, from 0.16 to 0.75 ppm in peach and from 0.08 to 0.57 ppm in plum. The data support an MRL of 1.7 ppm for the stone fruit crop group (CG 12). However, additional trials will be needed to meet the requirements outlined by the PMRA. Four additional trials (3 trials carried out in zone 5 and 1 trial from zone 11) carried out in peaches are needed as well as three additional trials carried out in plums (one trial in each of zones 1A, 5 and 11) are required. No additional cherry trials are required.

Primary use on: Berries (Crop Group 13)	The crops of the berry crop group are on the proposed Canadian label. The residue trials in high bush blueberries and raspberries were carried out at 1.07× gap and a PHI of 0 days. Nine field trials, including a decline trial, were conducted on highbush blueberries (6) (but none of the trials were carried out in lowbush blueberries) and red raspberries (3), the representative crops of the berry crop group, using the proposed use pattern. Samples were stored frozen 3.2 months prior to residue analysis. The freezer storage stability of the residue in these matrices demonstrated over the time span was acceptable. LC/MS/MS method D9908 was validated and used for the quantitation of the residue. Quantifiable residues of BAS 510 F were reported in all trials. Residues ranged from 0.49 to 2.5 ppm in blueberries and from 1.4 to 3.3 ppm in raspberries (HAFT = 2.7 ppm). The data supports an MRL of 3.5 ppm for the berries crop group (CG-13); however, additional residue trials are needed because the submitted residue data does not meet the zonal requirements set out in the DIR98-02. Two regulatory options are outlined below: Option one: Sufficient data are available for the PMRA to support a registration on high bush blueberries only and a national registration on the remaining crops within this crop group provided additional residue trials in raspberries are carried out and submitted. One trial in each of zones 5 and 5A and required. Option two: A total of four additional residue trials (two trials in each of zones 1A and 5A) carried out in blueberries (low bush) as well as two additional raspberry trials (one trial in each of zones 5 and 5A) would be required to support a domestic registration.

Primary use on: Tree Nuts (Crop Group 14) and Pistachio	Tree nuts are not on the proposed Canadian label. These data were submitted in support of a request to establish an MRL for imported crops. Ten field trials, including a decline trial, were conducted on almonds (5) and pecans (5), the representative crops of the tree nuts crop group, using the proposed U.S. use pattern. As tree nuts are not a commercial crop in Canada, there is no potential for a domestic registration of this chemical on these crops. We note however that the number and location of trials meet the USEPA's requirements for the tree nut crop group. Samples of almond nutmeats and hulls and pecan nutmeats were stored frozen for 4.3 months prior to analysis. Acceptable supporting freezer storage stability data are available. LC/MS/MS method D9908 was validated and used for the quantitation of the residue. Quantifiable residues (0.05 ppm) of BAS 510 F were reported in/on all almond hulls samples, in almond nutmeats from 3 of the 5 trials and not in any samples of pecan nutmeats. Residues ranged from 0.42 to 2.84 ppm (HAFT = 2.45 ppm) in almond hulls, from <0.05 to 0.20 ppm in almond nutmeats and were <0.05 ppm in all pecan nutmeats. Primary use on: Pistachio. Pistachios are not grown in Canada. Three pistachio field trials were conducted under the proposed U.S. use pattern. The number and location of trials meet the USEPA's requirements for pistachio. Nutmeat samples were stored frozen for 3.4 months prior to analysis. Acceptable supporting freezer storage stability data are available. LC/MS/MS method D9908 was validated and used for the quantitation of the residues. Quantifiable residues of BAS 510 F were reported in two of the three trials. Residues ranged from <0.05 to 0.64 ppm. **Rationale in support of an MRL on the tree nut crop groups (Crop Group 14) and pistachio** The crops of the tree nut crop group as well as pistachios are not commercially grown in Canada. The USEPA has considered the residue data submitted by BASF. Due to the variability of the data, the USEPA's ChemSAC (4/16/03 meeting) was consulted. The USEPA concluded that the currently available field trial data are appropriate for the establishment of both a tree nut crop group tolerance and a pistachio tolerance at 0.70 ppm. This was the preferred approach recommended by B. Schneider, HED's commodity definition and cultural practices expert. It is also the approach that will most easily facilitate transition to the new tree nut crop group definition which is proposed by IR-4 and USEPA to include pistachio. Tolerances at 0.7 ppm for the tree nut crop group (CG 14) and, as a separate listing, for pistachio per se will be established in the U.S. The PMRA agrees with the reasoning of the USEPA's expert committee and will also recommended the promulgation of an MRL of 0.7 ppm for both the tree nut crop group and pistachios.

Primary use on: Oilseeds Crop Group 20	Only canola is currently on the proposed Canadian label. The residue trials were carried out at 1.47× gap and a PHI of 21 days. Sixteen canola trials, including two decline trials, were conducted in accordance with the proposed use pattern. An additional test plot at four of the trial sites was treated at a 3× rate to produce higher residues for processing. Samples were stored frozen for 4.8 months prior to analysis. Acceptable freezer storage stability data are available. LC/MS/MS method D9908 was validated and used for the quantitation. Quantifiable residues of BAS 510 F were reported in all samples. Residues ranged from <0.14 to 3.42 ppm (HAFT=3.2 ppm) in 1× rate samples and from 0.58 to 5.1 ppm in 3× rate samples. The number and location of trials were sufficient to the meet PMRA residue chemistry guidelines (DIR98-02). No additional canola trials are required by the PMRA. Sunflowers are not on the proposed Canadian label. Seven sunflower crop field trials were conducted and seed samples were collected for analysis. An additional test plot at 1 of the trial sites was treated at a 5× rate to produce higher residues for processing. Samples were stored frozen for 2.8 months prior to analysis. Adequate freezer storage stability data are available. LC/MS/MS method D9908 was validated and used for the quantitation. Quantifiable residues of BAS 510 F were reported in all trials. Residues (1× rate) ranged from <0.05 to 0.54 ppm (HAFT = 0.45 ppm). The number and location of trials were sufficient and no additional trials are required by the PMRA. **Rationale for not supporting an MRL on the oilseed crop group (Crop Group 20)** The maximum residue from the sunflower field trials was 0.539 ppm. The maximum residue from canola field trials by the same use pattern was 3.42 ppm. These maximum residues vary by more than a factor of 5.0×, thus rendering a crop group MRL for the Oilseed crop group inappropriate. An MRL of 3.5 ppm will be recommended to cover the residues of BAS 510 in canola and an MRL of 0.6 will be recommended to cover potential residues in sunflower seed.
Primary use on: Grapes	Grapes are on the proposed Canadian label. The residue trials were carried out at 1.1× gap and a PHI of 14 days. Twelve field trials, including one decline trial, were conducted on grapes at the proposed use pattern. An additional test plot in one trial was treated at a rate of 5× gap to provide higher residues for processing. Samples of grapes collected in the U.S. trials were stored frozen for 3.4 months prior to analysis. Acceptable freezer storage stability data are available. LC/MS/MS method D9908 was validated and used for the quantitation of the residues. Quantifiable residues of BAS 510 F were reported in all samples. Residues ranged from 0.27 to 3.1 ppm (1× rate) and from 4.7 to 4.9 ppm (5× rate). The data support an MRL of 3.5 ppm for grapes. For grapes, the PMRA's residue data requirements have not been met. As a condition of registration, four additional trials in zone 5 are required by the PMRA.

Primary use on: Mint	Mint is not on the current Canadian label. Five crop field trials were conducted on peppermint (4) and spearmint (1) in accordance to the proposed use pattern. Samples of mint tops were collected at 7- and 14–15 day PHI. An additional trial was conducted at a rate of 5× gap to produce higher residues for processing. Samples collected in the submitted studies were stored frozen for 3.6 months prior to analysis. Acceptable freezer storage stability data are available. LC/MS/MS method D9908 was validated and used for the quantitation. Quantifiable residues of BAS 510 F were reported in all samples. Residues (1× rate) ranged from 6.7 to 36.4 ppm (7-day PHI) and 4.8–28.6 ppm (14–15 day PHI). The data support a primary MRL of 30.0 ppm for the tops of peppermint and spearmint (in conjunction with a 14-day PHI). The geographical representation was insufficient for PMRA. DIR98-02 does not specify trial requirements for mint. As a condition of registration for BAS 510 on any crop, two trials carried out in the major growing regions of Alberta would be needed to support the domestic registration on mint.
Primary use on: Peanut	Peanuts are an imported crop. Twelve field trials, including one decline trial, were conducted on peanut (nutmeat and hay) under the proposed use pattern on the U.S. label. An additional test plot in one trial was treated at 3× rate to provide higher residues for processing. The number and location of trials meet the USEPA's requirements. Samples from these trials were stored frozen for 4.3 months prior to analysis. Acceptable supporting freezer storage stability data are available. LC/MS/MS method D9908 was validated and used for quantitation of the residues in these samples. Non-quantifiable residues (<0.05 ppm) of BAS 510 F were reported in all but one (0.054 ppm) sample of peanut nutmeats, including those treated at the 3× rate. The data support a MRL of 0.05 ppm for peanut nutmeat.
Primary use on: Strawberry	Strawberries are on the proposed Canadian label. The residue trials were carried out at 1.06× gap and a PHI of 0 days. Eight strawberry field trials, including a decline trial, were conducted in accordance with the label. Samples were stored frozen 5 months prior to analysis. Acceptable freezer storage stability data are available. LC/MS/MS method D9908 was validated and used for quantitation of the residue. Quantifiable residues of BAS 510 F were reported in all trials. Residues ranged from 0.16 to 1.16 ppm (HAFT = 1.00 ppm). The data support an MRL of 1.2 ppm for strawberries. The residue data does not completely fulfill the PMRA's residue data requirements. Based on the magnitude of the residues observed in the various trials as well as the rapid dissipation of the residue, the PMRA will not require additional residue trials as a condition of registration in Canada.

Field Accumulation Studies in Rotational Crops	Two strawberry (primary crop) field trials were conducted under the proposed use pattern on strawberries and the crop harvested. Three representative rotational crops (cabbage, radish and winter wheat) were planted into the soil 14, 30 and 45 days following the last application to the primary crop. Samples of the rotational crop commodities (cabbage heads with and without wrapper leaves, radish roots and tops, and winter wheat forage, hay, straw and grain) were harvested at normal maturity and stored frozen up to 12.5 months prior to analysis. Acceptable supporting freezer storage stability data are available. LC/MS/MS method D9908 was validated and used for the quantitation of the resulting residues in all matrices. Quantifiable residues (0.05 ppm) were not present in cabbage from any plantback interval (PBI). All radish and wheat samples (except wheat grain) contained quantifiable residues at all PBIs. Since quantifiable residues were observed at the longest (45-day) PBI studied, extended rotational crop field trials are required to support the establishment of MRLs needed to cover the rotational residue/secondary residues in rotational crop commodities.

Extended Rotational Crop Field Trials	Twenty-one extended field accumulation trials were conducted on representative crops, cowpea (3), field pea (3) and soybean (15) of Crop Group 7. The number and geographic distribution of trials is acceptable to the PMRA. Each crop was planted, as a rotational crop, into treated soil (total of 2 kg a.i./ha applied), 13–15 days after the last application. Samples of bean (forage and hay), field pea (vines and hay) and soybean (forage, hay and seed) were collected at appropriate sampling intervals or at normal maturity. Samples were stored frozen up to 4.6 months prior to analysis. Acceptable supporting storage stability data are available. LC/MS/MS Method D9908 was validated and used for the quantitation of the residues in the harvested commodities. Residues of BAS 510 F ranged from <0.05 to 1.05 ppm in the forages, <0.05–1.50 ppm in the hays, and were <0.05 ppm in the vines and all but one (0.06 ppm) soybean seed sample. An MRL of 0.1 ppm soybean seed per se (of Crop Group 6) are recommended. As the remaining commodities are animal feed items, no MRLs need to be promulgated for these commodities. A PBI of 14-day is required on the label. Thirty-four extended field accumulation trials were conducted on the representative crops, corn (field and sweet), rice, sorghum and wheat (spring and winter) to cover off the crops in crop groups 15 and 16. The number and geographic distribution of trials were based on an agreement with the USEPA. As some of the trials were carried out in zones common to both countries, the PMRA can accept the distribution of the trials as being sufficiently representative. Each crop was planted, as a rotational crop, into treated soil (total of 2 kg a.i./ha applied), 13–19 days after the last application. Samples of corn (forage, kernel + cob with husk removed, grain and stover), rice (grain and straw), sorghum (forage, grain and stover) and wheat (forage, hay, grain and straw), were collected at appropriate sampling intervals or at normal maturity. Samples were stored frozen up to 5.5 months prior to analysis. Acceptable supporting storage stability data are available. LC/MS/MS Method D9908 was validated and used for the quantitation of the residue. Residues of BAS 510 F ranged from <0.05 to 1.37 ppm in the forages, <0.05–0.50 ppm in the stovers, <0.05–2.7 ppm in the straws, <0.05–0.99 ppm in hay and <0.05–0.13 ppm in the grains. The study is acceptable. An MRL is needed to cover rotational residues/secondary residues in Crop Group 15. An MRL of 0.20 ppm for the grains of Crop Group 15 crops is appropriate (in conjunction with a 14-day PBI). Twelve extended field accumulation trials were conducted on representative grasses (bluegrass, Bermuda grass, bromegrass, ryegrass and tall fescue Crop Group 17). The number and geographic distribution of trials meet U.S. requirements. The grasses were planted, as rotational crops, into treated soil (total of 1.9–2.0 kg a.i./ha applied), 12–15 days following the last application. Grass (forage, hay, seed screening and straw) samples were collected at normal maturity. Samples were stored frozen for <6.5 months prior to analysis. Adequate supporting freezer storage stability data are available. LC/MS/MS Method D9908 was validated and used for the quantitation of the residues. Residues of BAS 510 F ranged from 0.07–1.9 ppm in grass forage, 0.18–7.1 ppm in grass hay, 0.06–0.10 ppm in grass seed screening and 0.12–0.22 ppm in grass straw. A 14-day PBI is required on the label.

	Fourteen extended field accumulation trials were conducted on the representative crops, alfalfa and clover (Crop Group 18). The number and geographic distribution of trials were based on an agreement with the USEPA. Alfalfa and clover were planted, as rotational crops, into treated soil (total of 1.9–2.0 kg a.i./ha applied), 12–15 days following the last application. Alfalfa (forage, hay and seed) and clover (forage and hay) samples were collected at appropriate sampling intervals or at normal maturity. Samples were stored frozen for <6 months prior to analysis. Adequate supporting storage stability data are available. LC/MS/MS Method D9908 was validated and used for the quantitation of the residue. Residues of BAS 510 F ranged from <0.05–0.57 ppm in the forages and <0.05–1.59 ppm in the hays, and were <0.05 ppm in alfalfa seed. A 14-day PBI is required on the label. Nine extended field accumulation trials were conducted in cottonseed. The number and geographic distribution of trials meet U.S. requirements. Cotton was planted, as a rotational crop, into treated soil (total of 2 kg a.i./ha applied), 13–15 days following the last application. At maturity, samples of cottonseed and cotton gin by-products were collected by hand (3 trials; cottonseed only), picker (3 trials), or stripper (3 trials), and stored frozen for <4 months prior to analysis. Supporting storage stability data are available. LC/MS/MS Method D9908 was validated and used for the quantitation of the residue. Residues of BAS 510 F were non-quantifiable (<0.05 ppm) in all cottonseed samples and <0.05–0.20 ppm in/on cotton gin by-products. An MRL of 0.05 ppm (LOQ) for cottonseed will be recommended. An MRL of 3.5 ppm for flax seed will be promulgated to cover residues in flax seed grown as a rotated crop. This tolerance is supported by conventional crop field trial data on canola seed. Thus, the proposed rotational crop MRL is considered to be ultra-conservative. As with all the rotational crops, a 14-day PBI is required on the proposed label.
RESIDUE DECLINE	Residue decline information was generated in 26 different commodities. Due to the large variation in the predicted decline for the various matrices, only the general conclusion that residues of BAS 510 decrease with time is supported.

PROCESSED FOOD/FEED	Canola seed, bearing BAS 510 F residues of 0.72–2.3 ppm, were processed into meal and refined oil using simulated commercial processing procedures. Samples were stored frozen, canola seed samples were analyzed within 8.5 months of harvest and processed samples within 3.2 months. Adequate supporting storage stability data are available. LC/MS/MS method D9908 was used for quantitation. BAS 510 F residues reduced in canola meal (to an average 0.48×) and concentrated slightly in refined oil (average 1.31×). A separate MRL of 5.0 ppm is needed for canola oil. Grapes, bearing BAS 510 F residues of 4.7 and 4.9 ppm, were processed into juice and raisins using simulated commercial processing procedures. Samples of grapes, grape juice and raisins were stored frozen up to 3.4, 2 and 1 month, respectively, prior to analysis. Adequate data are available to support the storage stability of the grape RAC samples. Data are required to support the storage conditions and intervals (61 days) of the grape juice samples; submission of these data is required as a condition of registration. Storage stability data are not required for raisins since samples were analyzed within 1 month of collection. LC/MS/MS method D9908 was used for quantitation. BAS 510 F residues reduced in grape juice (to 0.45× average) and concentrated in raisins (average 2.42×). An MRL of 8.5 ppm for raisins is therefore recommended. Mint hay, bearing BAS 510 F residues of 81–103 ppm, were processed into oil using simulated commercial processing procedures. Samples of mint hay and oil were stored frozen up to 2 months prior to analysis. Supporting storage stability data are available. LC/MS/MS method D9908 was used for quantitation. Residues of BAS 510 F reduced in mint oil (to <0.01×). The submitted study is acceptable. Residues in mint oil will therefore be covered by the MRL on the RAC. Peanuts, bearing BAS 510 F residues below the LOQ (<0.05 ppm), were processed into meal and refined oil using simulated commercial processing procedures. Samples of peanut nutmeat, meal and refined oil were stored frozen for 70, 41 and 37 days, respectively, prior to analysis. Supporting storage stability data are available. LC/MS/MS method D9908 was used for quantitation. BAS 510 F residues apparently concentrated in peanut meal (7.8× average) and refined oil (9.2× average). As all of the residues in the starting material were below the LOQ, the calculation of the apparent concentration factors is not scientifically sound. An appropriate MRL for peanut oil at 0.15 ppm is proposed, based on the TMCF.

	Plums, bearing BAS 510 F residues of 0.68 and 1.1 ppm, were processed into washed plums and prunes, using simulated commercial processing procedures. Samples of plums and prunes were stored frozen for up to 99 and 78 days, respectively, prior to analysis. Adequate supporting storage stability data are available. LC/MS/MS method D9908 was used for quantitation. Residues of BAS 510 F reduced in prunes to an average 0.52×. The MRL on the RAC will therefore cover the residues in processed commodities. Rice and wheat grown as rotational crops in soil pretreated with BAS 510 F were used in this study. Rice grain, with BAS 510 F residues below the LOQ (<0.050 ppm), was processed into polished rice, hulls and bran, the currently regulated processed commodities of rice. Wheat grain, with BAS 510 F residues below the LOQ (<0.050 ppm), was processed into bran, flour, shorts, germ and middling, the currently regulated processed commodities of wheat. Grain samples were stored frozen for <3.5 months and processed samples <2 weeks before analysis. Adequate supporting freezer storage stability data are available. LC/MS/MS method D9908 was used for quantitation. Residues of BAS 510 F were non-quantifiable (<0.050 ppm) in polished rice and rice bran and concentrated in rice hulls (average 2.6×). The TMCF in rice hulls is 5.0×. Residues of BAS 510 F concentrated slightly (average 1.2×) in wheat bran and germ, and were non-quantifiable (<0.050 ppm) in wheat flour, shorts and middling. The MRL on the RAC will therefore cover any potential residues in the processed grain commodities. Soybean seed, bearing BAS 510 F residues of 0.25–0.37 ppm, were processed into hulls, meal and oil using simulated commercial processing procedures. Samples were stored frozen and analyzed within 1 month of collection. LC/MS/MS method D9908 was used for quantitation. Residues of BAS 510 F reduced in soybean meal (to <0.2×) and oil (to 0.4×) and concentrated in hulls (1.8×). The MRL on the RAC will therefore cover any potential residues in the processed soybean commodities. Sunflower seed, bearing BAS 510 F residues of 2.4–5.0 ppm, were processed into meal and oil, using simulated commercial processing procedures. Samples were stored frozen until analysis (within one month of harvest). LC/MS/MS method D9908 was used for quantitation. BAS 510 F residues reduced (to <0.1×) in sunflower meal and oil. The MRL on the RAC will therefore cover any potential residues in the processed sunflower commodities. Tomatoes, bearing BAS 510 F residues of 0.62–1.5 ppm, were processed into puree and paste, the currently regulated processed commodities of tomato using simulated commercial processing procedures. Samples of tomatoes, tomato puree and tomato paste were stored frozen for up to 147, 131 and 154 days, respectively, prior to analysis. No storage stability data are available to support the storage conditions and duration of tomato puree and paste samples; these data are required, as a condition of registration. LC/MS/MS method D9908 was used for quantitation. Residues of BAS 510 F reduced in puree (to an average 0.35×) and concentrated slightly in paste (average 1.06×). The MRL on the RAC will therefore cover any potential residues in the processed commodities.

DAIRY CATTLE FEEDING	Lactating dairy cows consumed BAS 510 F-laced feed for 29–30 days at levels equivalent to 1.8, 5.9 and 20.2 ppm in the diet. Based on the residue data obtained from treated crops and calculations of maximum theoretical dietary burdens to livestock using "worst case" diets MRLs ranging from 0.10 to 0.35 ppm are being proposed
POULTRY FEEDING	Laying hens were dosed daily for 29 days via balling gun with encapsulated BAS 510 F at levels equivalent to 1.0, 5.3 and 19.6 ppm in the diet. Based on the residue data obtained from treated crops and calculations of maximum theoretical dietary burdens to livestock using "worst case" diets appropriate animal MRLs ranging from 0.02 to 0.10 ppm are being proposed.

PROPOSED MRLs

Proposed MRLs for BAS 510 (plant and animals)

Proposed MRL	Commodities
30	peppermint, tops; spearmint, tops
18	broccoli raab; cabbage, Chinese; bok choy; collards; kale; mustard greens; mustard spinach; rape greens
11	lettuce, leaf
8.5	raisin
6.5	lettuce, head
5	canola oil
3.5	blackberry; blueberry; caneberry; currant; elderberry; flax; gooseberry; grape; huckleberry; linseed; loganberry; mustard seed; mustard seed, field; mustard seed, Indian; rape seed; rape seed, Indian; raspberry
3	broccoli; broccoli, Chinese; Brussel sprouts; cabbage; cabbage, Chinese mustard; cabbage, Chinese napa; cauliflower; garlic, bulb; garlic, great headed; garlic, great headed, bulb; kohlrabi; leek; onion, dry bulb; onion, green; onion, potato; onion, potato, bulb; onion, tree; onion, tree, top; onion, Welsh; onion, Welsh, tops
2.5	bean, adzuki; bean, broad dry; bean, dry; bean, kidney; bean, lablab; bean, lima dry; bean, moth; bean, mung; bean, navy; bean, pink; bean, pinto; bean, rice; bean, tepary; bean, urd; catjang; chickpea; cowpea; guar; lentil; lupin, grain; lupin, sweet; pea, black-eyed; pea, crowder; pea, field; pea, field seed; pea, pigeon; pea, southern
1.7	apricot; cherry, sweet; cherry, tart; nectarine; peach; plum; plum, chickasaw; plum, damson; plum, Japanese; plum, prune; plum, prune, fresh
1.6	bean, moth; bean, runner; bean, snap; bean, wax; bean, yardlong; jackbean; longbean, Chinese; pea, dwarf; pea, edible podded, pea, pigon; pea, snow; pea, sugar snap; swordbean
1.5	balsam apple; balsam pear; cantaloupe; chayote, fruit; gherkin; West Indian, gourd, edible; melon; melon, citron; muskmelon; pumpkin; squash; squash, summer; squash, winter; watermelon; waxgourd, Chinese
1.2	strawberries

PROPOSED MRLs	**Proposed MRLs for BAS 510 (plant and animals)**	
	Proposed MRL	**Commodities**
	1	amaranth leafy; arugula; bamboo; beet, fodder, top; beet, garden, top; beet, sugar, top; beet, sugar; burdock, edible, top; cardoon; carrot, top; cassava, leaves; celery; celery Chinese; celtuce; chili; chervil; chervil, fresh leaves; chicory, tops; chrysanthemum, edible leaved; chrysanthemum, garland; corn salad; cress, garden; cress, upland; dandelion leaves; dasheen, leaves; dock; eggplant; endive; fennel, Florence; fennel, Florence, fresh leaves and stalk; groundcherry; kale, sea; orach; orach, leaves; parsley; parsley, leaves; parsnip, tops; pepino; pepper; pepper, bell; pepper, non-bell; pepper, non-bell, sweet; purslane, garden; purslane, winter; radicchio; radish oriental, tops; radish tops; rhubarb; rutabaga, top; salsify, black, tops; spinach; spinach, Chinese; spinach, New Zealand; spinach, vine; Swiss chard, tampala; tanier, leaves; taro, leaves; tomatillo; tomato; turnip rooted, tops; turnip, tops; yam, true, leaves
	0.7	almond; beechnut; burdock, edible carrot; butternut; carrot; cashew; celeriac; chervil, turnip rooted; chestnut; chicory, root; chinquapin; filbert; ginseng; hickory, nut; horseradish; nut, Brazil; nut, hickory; nut, macadamia; rooted, parsnip; parsley, turnip rooted; parsnip; pecan; pistachio; radish; radish, oriental; rutabaga, salsify; salsify, black; salsify; Spanish, skirret; turnip; walnut
	0.6	bean, broad succulent; bean, lima succulent; pea, black-eyed; pea, English; pea, garden; pea, green; pea, pigeon; pea, southern; safflower; sunflower seed
	0.35	meat by-product of cattle, goats, hogs, horses and sheep
	0.3	fat of cattle, goats, hogs, horses and sheep
	0.2	barley; buckwheat; corn, field; corn, pod; corn, pop; corn, sweet; cucumber; cucumber, Chinese; millet; millet, pearl; millet, proso; oat; rice; rice, wild; rye, sorghum; grain, teosinte; triticale; wheat; wheat, vavilovi; wheat, wild einkorn, wheat, wild emmer
	0.15	peanut oil
	0.1	meat of cattle, goats, hogs, horses and sheep, milk, poultry meat by-products, soybean

PROPOSED MRLs	**Proposed MRLs for BAS 510 (plant and animals)**	
	Proposed MRL	**Commodities**
	0.05	arracacha; arrowroot; artichoke, Chinese; artichoke, Jerusalem; canna, edible; cassava; chayote root; chufa; cotton seed; dandelion; dasheen; ginger; leren; peanut; potato; sweet potato; poultry meat and fat; tanier; taro; turmeric; yam, bean; yam, true
	0.02	egg
U.S. TOLERANCES		
BAS 510 F: PRIMARY CROP TOLERANCE PROPOSALS		
	Vegetable, root (except sugar beet), subgroup 1B, excluding garden beet, radish and turnip	0.7
	Vegetable, tuberous and corm, subgroup 1C	0.05
	Vegetable, bulb, group 3	3
	Lettuce, head; Lettuce, leaf	6.5 11.0
	Vegetable, *Brassica* leafy, head and stem, subgroup 5A	3
	Vegetable, *Brassica* leafy, leafy greens, subgroup 5B	18
	Edible podded legume vegetable subgroup 6A	1.6
	Succulent shelled pea and bean subgroup 6B	0.6
	Dried shelled pea and bean subgroup 6C	2.5
	Vegetable, fruiting, group 8	1.0
	Vegetable, cucurbit, group 9 (except cucumber) Cucumber	1.7 0.25
	Fruit, stone, group 12	1.7
	Berries, group 13	3.5
	Nut, tree, group 14	0.7
	Almond, hull	3
	Pistachio	0.7

PROPOSED MRLs	**Proposed MRLs for BAS 510 (plant and animals)**	
	Proposed MRL	**Commodities**
	Grape	3.5
	Raisin	8.5
	Strawberry	1.2
	Peanut, nutmeat	0.05
	Peanut, meal	0.15
	Peanut, oil	0.15
	Canola, seed	3.5
	Canola, oil	5.0
	Sunflower, seed	0.6
	Peppermint, tops	30.0
	Spearmint, tops	30.0
BAS 510 F: ROTATIONAL CROP TOLERANCE PROPOSALS		
	Beet, garden, root	1.0
	Radish, root	1.0
	Turnip, root	1.0
	Beet, sugar, root	1
	Vegetable, root and tuber, leaves, group 2	1
	Vegetable, leafy, group 4 (except lettuce)	1
	Vegetable, legume, foliage, group 7, forage	1.5
	Vegetable, legume, foliage, group 7, hay	2.0
	Vegetable, legume, foliage, group 7, vines	0.05
	Grain, cereal, group 15	0.2
	Rice, hulls	0.5
	Grain, cereal, forage, fodder and straw, group 16, forage	2.0
	Grain, cereal, forage, fodder and straw, group 16, straw	3.0
	Grain, cereal, forage, fodder and straw, group 16, fodder	1.5

PROPOSED MRLs	**Proposed MRLs for BAS 510 (plant and animals)**	
	Proposed MRL	**Commodities**
	Grass, forage, fodder and hay, group 17, forage	2.0
	Grass, forage, fodder and hay, group 17, hay	8.0
	Grass, forage, fodder and hay, group 17, straw	0.30
	Grass forage, fodder and hay, group 17, seed screening	0.20
	Feed, non-grass, animal, group 18, forage	1.0
	Feed, non-grass, animal, group 18, hay	2.0
	Feed, non-grass, animal, group 18, seed	0.05
	Cotton, seed	0.05
	Cotton, gin by-products	0.3
	Soybean, seed	0.1
	Soybean, hulls	0.2
	Cowpea, seed	0.10
	Lupin, grain	0.10
	Pea, field, seed	0.10
	Flax, seed	3.5
BAS 510 F + Hydroxy Metabolite: ANIMAL COMMODITY TOLERANCE PROPOSALS		
	Milk	0.1
	Cattle, meat	0.1
	Cattle, fat	0.3
	Cattle, meat by-products	0.35
	Eggs	0.02
	Poultry, meat	0.05
	Poultry, fat	0.05
	Poultry, meat by-products	0.1
	Goat, meat	0.1
	Goat, fat	0.3
	Goat, meat by-products	0.35
	Hog, meat	0.05

PROPOSED MRLs	**Proposed MRLs for BAS 510 (plant and animals)**	
	Proposed MRL	**Commodities**
	Hog, fat	0.1
	Hog, meat by-products	0.1
	Horse, meat	0.1
CODEX MRLs	none	

Table 2 Summary of the analytical methods

Analytical methodology		
Parameter	***Plant***	***Animal***
Method ID	Data Collection Method: D9908 Enforcement Method: D0008	Data Collection Method: D471/0 and 476/0 Enforcement Method: DFG S19
Analytes	Parent	The combined residues of BAS 510 F and its hydroxy metabolite, free (M510F01) and bound (M510F02), all expressed in parent equivalents.
Instrument/ detector	**Method D9908: LC/MS/MS**: The LC system utilizes an Intersil Phenyl 5 m® column (C_{18}) and an isocratic mobile phase of methanol:4 mM ammonium formate:0.1% formic acid (80:19.9:0.1, v:v:v). MS/MS detection using the positive ionization mode monitors ion transitions from m/z 343 to 307. Quantitation is obtained using an external calibration curve of BAS 510 F standards. **Method D0008: GC/MS (SIM):** Residues are redissolved with 0.01% polyethylene glycol (M_n ca. 400) in toluene and analysed using GC/MS with selected ion monitoring (SIM). The method lists monitoring ions of *m/z* 342, 142, or 140, and notes that any ion can be used for quantitation based on the cleanness of the chromatograms. Quantitation is performed using an external calibration curve of BAS 510 F standards.	**Method D471/0: LC/MS/MS** The HPLC system utilizes a High Purity Elite C18 column and a gradient mobile phase of water, methanol and formic acid. MS/MS detection using the positive ionization mode monitors ion transitions from m/z 359 to 140 and 323 for BAS 510 F and m/z 343 to 140 and 307 for M510F01. Quantitation is conducted using an external calibration curve of BAS 510 F and M510F01 standards. **Method 476/0: GC/MS (SIM)** Method 476/0 was developed to determine nonextractable residues of BAS 510 F in liver and milk. The method is a common moiety method based on the quantification of the metabolite M510F53. Microwave hydrolysis experiments revealed that this conjugation modified the reactivity of the whole molecule, allowing the amide bond to be cleaved during microwave treatment. If the microwave hydrolysis was conducted using acetic acid, metabolite M510F53 could be generated. The hydrolysis of the amide bond was not observed during microwave treatment of the parent or its metabolite M510F01. Therefore, M510F53 is used as a marker analyte for bound residues of BAS 510 F in liver. The microwave hydrolysis techniques were also applied to milk samples in the goat metabolism study, theoretically releasing conjugated residues of BAS 510 F. The residues are dissolved in ACN for GC/MS analysis. The MS detector uses selected ion monitoring (SIM); ion m/z 167 was detected for M510F53. For method validation, samples of milk and cow liver hydrolysates were fortified with M510F53 in acetonitrile (ACN) after the microwave hydrolysis step. Quantitation is obtained using an external calibration curve of M510F53 standards.

Analytical methodology		
Parameter	***Plant***	***Animal***
		Method DFG S19: GC/ECD The GC system uses a Varian Chrompack CP Sil 8 column and electron capture detection. Quantitation is obtained using an external calibration curve of standards of BAS 510 F and the acetyl derivative of M510F01. The M510F01 acetyl derivative standards are calculated as BAS 510 F equivalents when determining the calibration curve; thus, residues of M510F01 are reported as BAS 510 F equivalents.
Standardization method	An external bracketing standard of BAS 510 is used in the analysis of multiple matrices.	External bracketing standards of BAS 510, BAS 510 F01 and BAS510F02 are used in the analysis of multiple matrices.
Stability of primary and/or secondary standard solutions	Standard solutions (acetonitrile, solvent) of BAS 510 F and various of its metabolites (M510F01, M510F49, M510F51 and M510F53) were tested and found to remain stable during 62 days of storage (duration of study), either refrigerated in the dark or at room temperature with daylight exposure.	
Retention times	**Method D9908**: 2:21min **Method D0008**: 3:30 min	**Method D471/0:** BAS 510: 3 min, BAS 510 F01: 7–8 min **Method D476/0:** BAS 510 determined as BAS 510 F53 (after microwave extraction): 9.0 min. **Method DFG S19:** For BAS 510, 10.1 min. For BAS 510 F01, 13.6 min
Limit of detection (LOD); limit of quantitation (LOQ)	**Method D9908**: LOQ = 0.05 LOD, 5 pg/μL **Method D0008**: LOQ = 0.05 LOD, 2 pg/μL	**Method D471/0:** For both parent and BAS 510F01, 0.01 ppm in eggs, milk and cream and 0.025 ppm in meat, fat, kidney and liver. The LOD was not determined. **Method 476/0:** BAS 510 determined as BAS 510 F53 (after microwave extraction): 0.05 and 0.01 ppm for liver and milk respectively. **Method DFG S19:** For both parent and the hydroxy metabolite expressed as parent equivalents: For milk, LOQ = 0.1 ppm, LOD = 0.002 ppm. For meat, fat and eggs, LOQ = 0.025 ppm, LOD = 0.005 ppm
Repeatability/ precision	**Method D9908:** Acceptable recoveries were obtained in multiple matrices over a wide range of spiking levels. **Method D0008:** Acceptable recoveries were obtained in multiple matrices over a wide range of spiking levels.	**Method D471/0:** Acceptable recoveries were obtained in multiple matrices over a wide range of spiking levels. **Method 476/0:** Acceptable recoveries were obtained in multiple matrices over a wide range of spiking levels. **Method DFG S19:** Acceptable recoveries were obtained in multiple matrices over a wide range of spiking levels for both parent and the hydroxy metabolite.

Analytical methodology		
Parameter	***Plant***	***Animal***
Reproducibility	An ILV of GC/MS enforcement **Method D0008** was conducted to verify the reliability of the method for the determination of BAS 510 residues in/on canola and tomato. The recovery values obtained (75–108% in snap beans, 81–114% in canola seed, 91–108% in canola oil, 85–123% in lettuce, 78–100% in peanut nutmeat and 86–117% in tomato) with the ILV initial trial indicate that the method D0008 is reliable at the method LOQ (0.05 ppm) and higher (70× LOQ).	An ILV of GC/MS enforcement **Method DFG S19**, was conducted to verify the reliability of the method for the determination of BAS 510 residues in/on multiple animal commodities. The recovery values obtained (91–101% and 105–136% (86–114% corrected) in milk and 71–77% and 86–99% in bovine liver) for both parent and the metabolite BAS 510-01 indicate that the method was reproducible at the LOQ and at 10 × LOQ.
Linearity	**Method D9908:** Demonstrated over the range of 0.1–10 pg/µL (r = 0.998). **Method D0008:** Demonstrated over the range of 2–20 ng/mL r = 0.993).	**Method D471/0:** For BAS 510 linearity was demonstrated over the range of 0.025–0.25 ppm with correlation coefficient of >0.99. For BAS 510 F01, linearity was demonstrated over the range of 0.025–0.25 ppm with correlations coefficient (r) of >0.99 **Method 476/0:** For BAS 510 determined as BAS 510 F53 (after microwave extraction) linearity was demonstrated over the range of 0.02–0.2 ppm with correlations coefficients of >0.99 in both liver and milk. **Method DFG S19:** Demonstrated for both analytes in multiple matrices in the range of 0.01–0.25 ppm (as appropriate) correlations coefficients were all > 0.999.
Specificity	**Method D9908**: Control interferences in multiple matrices were <0.01 ppm. **Method D0008**: Control interferences in multiple matrices were <0.01 ppm.	**Method D471/0:** Control interferences in multiple matrices were <0.01 ppm. **Method 476/0:** Control interferences in multiple matrices were <0.01 ppm. **Method DFG S19:** Control interferences in multiple matrices were <0.01 ppm.
MULTIRESIDUE METHOD	Residues of BAS 510 F and its metabolite M510F01 were not adequately recovered using the multiresidue methods. Protocol A was not applicable. Protocol B was not applicable for BAS 510 F and yielded inconsistent recoveries of M510F01. Residues of BAS 510 F and its hydroxy metabolite M510F01 had good responses with GC/ECD on a DB-1 column under Protocol C. Neither analyte was recovered at 30% using Protocols D, E and F.	

Table 3 Summary of the analytical methods recoveries obtained

Crop Group	Specific matrix	Fortification range (ppm)	Range of Recoveries (%)	n	Mean Recovery ± SD (%)
Recoveries obtained in primary crops					
1B	Carrot	0.050, 1.0	72–87	4	80 ± 6
	Radish roots	0.050, 1.00	76–116	10	88 ± 12
	Radish tops	0.050–80.0	75–154	10	97 ± 13
1C	Potato, tuber	0.050, 1.00	74–107	14	91 ± 9
3	Onion, green	0.050, 1.0	85–102	3	95 ± 9
	Onion, dry bulb	0.050, 1.0	76–100	4	86 ± 11
4	Lettuce, head	0.05, 1.00, 20.00	79–92	10	84.9 ± 4.4
	Lettuce, leaf	0.05, 1.00, 20.00	78–97	6	84.0 ± 6.8
5	Broccoli	0.05–5.0	78, 84, 90, 90, 94, 98, 99, 102, 105, 106, 130	11	98 ± 14
	Cabbage with wrapper leaves	0.05–5.0	76–127	22	88 ± 13
	Cabbage without wrapper leaves	0.05–5.0	76–99		
	Mustard greens	0.05–100	84–129	8	110 ± 19
6	Dry bean	0.05–3.00	76–98	8	84 ± 7
	Snap bean	0.05, 1.00	68–84	4	79 ± 8
	Lima bean	0.05, 1.00	78–89	4	84 ± 5
	Dried shelled pea	0.05, 1.00	81–94	4	87 ± 5
	Succulent shelled pea	0.05, 1.00	69–99	4	84 ± 15
	Succulent edible-podded pea	0.05, 5.00	96, 118	2	107
8	Tomato	0.05, 1.0	75–107	7	93 ± 11
	Pepper, bell	0.05, 1.0	86–92	3	89 ± 3
	Pepper, chili	0.05, 1.0	87, 93	2	90

Crop Group	Specific matrix	Fortification range (ppm)	Range of Recoveries (%)	n	Mean Recovery ± SD (%)
9	Cantaloupe	0.05, 1.0	89, 109, 128	3	109 ± 20
	Cucumber	0.05, 1.0	90, 92	2	91
	Summer squash	0.05, 1.0	94, 98, 102, 120	4	104 ± 11
12	Cherry	0.05, 2.5	83–93	4	88 ± 4
	Peach	0.05–5.0	60–94	11	83 ± 10
	Plum	0.05–5.0	79–116	5	90 ± 15
13	Blueberry, highbush	0.05, 5.0	94, 104	2	99
	Raspberry, red	0.05, 5.0	91, 107	2	99
14	Almond hulls	0.05, 1.0	77–84	3	80 ± 4
	Almond nutmeat	0.05, 1.0	87, 90	2	89
	Pecan nutmeat	0.05, 1.0	73–82	4	78 ± 4
Canola	Canola seed	0.050–10.0	60–100	12	83 ± 12
Sunflower	Sunflower seed	0.050–1.00	78–104	6	94 ± 12
Strawberry	Strawberry	0.05, 1.0, 5.0	83–103	4	93 ± 8
Grape	Grape	0.05, 1.0	88–132	3	105 ± 23
Pistachio	Pistachio nutmeat	0.05, 1.0	71, 79	2	75
Peanut	Peanut, nutmeat	0.05, 1.00	66–81	6	72 ± 7
	Peanut, hay	0.05–30.0	72–100	8	83 ± 10
Mint	Mint tops	0.050–40.0	79–106	4	98 ± 12

Crop Group	Specific matrix	Fortification range (ppm)	Range of Recoveries (%)	n	Mean Recovery ± SD (%)
Recoveries obtained in rotational crops					
bean, forage and hay, field pea, vines and hay, soybean forage and hay of the foliage of Legume Vegetables group (Crop Group 7).	Bean, forage	1.00, 30.0	82, 108	2	95
	Bean, hay	0.05–20.0	64–95	3	82 ± 16
	Pea, vine	0.05, 1.0	103, 104	2	104
	Pea, hay	0.05–5.00	80–112	3	99 ± 17
	Soybean, forage	0.05, 1.00	82–98	6	93 ± 6
	Soybean, hay	0.05, 1.00	79–93	6	88 ± 5
17 & 18	Grass forage	0.05–2.0	73–107	6	91 ± 14
	Grass hay	0.05–10.0	41–108	8	87 ± 12
	Grass seed	0.05, 1.0	70, 99	2	85
	Grass straw	0.05, 1.0	92, 96	2	94
	Alfalfa forage	0.05–2.0	75–100	7	85 ± 9
	Alfalfa hay	0.05–2.0	72–91	6	79 ± 6
	Alfalfa seed	0.05, 1.0	82, 84	2	83
	Clover forage	0.05–2.0	72–90	4	81 ± 8
	Clover hay	0.05–2.0	73–91	4	79 ± 8
15	Corn, forage	0.050, 1.00	79–96	7	90 ± 6
	Corn, stover	0.050–3.00	82–104	6	87 ± 9
	Corn, grain	0.050, 1.00	70–123	6	97 ± 17
	Corn, fresh (K+CWHR)	0.050, 1.00	82–102	4	90 ± 9
	Rice, grain	0.050, 1.00	70, 83, 98	3	84 ± 14
	Rice, straw	0.050, 1.00	106, 118	2	112
	Sorghum, forage	0.050, 1.00	74–98	4	86 ± 12
	Sorghum, grain	0.050, 1.00	68–118	4	90 ± 24
	Sorghum, stover	0.050, 1.00	79–90	4	85 ± 6
	Wheat, forage	0.050–2.00	78–107	6	93 ± 11
	Wheat, hay	0.050–2.00	71–93	6	85 ± 8

Crop Group	Specific matrix	Fortification range (ppm)	Range of Recoveries (%)	n	Mean Recovery ± SD (%)
	Wheat, grain	0.050, 1.00	84–134	8	102 ± 15
	Wheat, straw	0.050–2.00	75–95	6	87 ± 8
Recoveries obtained in animal matrices (feeding studies)					
Hen	Method 471/0—BAS 510 F				
	Eggs	0.01	64, 65, 69, 71, 77	18	76 ± 11
		0.02	66, 75, 76, 82, 206		
		0.025	60		
		0.05	80, 83, 94		
		0.1	63, 71, 89, 98		
	Liver	0.025	66	2	66
		0.5	65		
	Muscle	0.025	66, 66	2	66
	Fat	0.025	64, 83	2	74
	Method 471/0—M510F01				
	Eggs	0.01	72, 72, 75, 96, 97	18	91 ± 149
		0.02	71, 80, 95, 96, 104		
		0.025	75		
		0.05	98, 101, 117		
		0.1	91, 97, 100, 109		

Crop Group	Specific matrix	Fortification range (ppm)	Range of Recoveries (%)	n	Mean Recovery ± SD (%)
Cow	Method 471/0—BAS 510 F				
	Milk	0.01	73.46–101.64	36	85.4 ± 7.6
		0.1	75.57–105.76		
	Skim milk	0.01	73.61, 81.67	4	81.5 ± 5.6
		0.1	83.94, 86.64		
	Cream	0.01	87.51, 90.13	4	89.8 ± 2.4
		0.1	88.70, 93.01		
	Muscle	0.025	89.73, 91.89	4	90.0 ± 4.5
		0.25	83.96, 94.58		
	Liver	0.025	82.44, 84.04	4	84.4 ± 6.7
		0.25	77.64, 93.67		
	Kidney	0.025	81.33, 97.59	4	85.8 ± 7.9
		0.25	81.23, 82.87		
	Fat	0.025	86.84, 88.37	2	89.6 ± 3.0
	Method 471/0—M510F01				
	Milk	0.01	69.34–99.72	36	85.7 ± 7.3
		0.1	76.04–102.93		
	Skim milk	0.01	80.76, 83.33	4	85.5 ± 4.4
		0.1	87.17, 90.70		
	Cream	0.01	71.72, 91.04	4	88.3 ± 11.5
		0.1	92.23, 98.15		
	Muscle	0.025	87.96, 93.11	4	90.8 ± 4.9
		0.25	85.77, 96.49		
	Liver	0.025	87.64, 89.70	4	85.4 ± 5.5
		0.25	77.25, 86.86		
	Kidney	0.025	88.38, 88.43	4	86.7 ± 2.1
		0.25	84.08, 85.94		
	Fat	0.025	73.59, 80.25	4	76.6 ± 2.8
		0.25	75.96, 76.42		

Crop Group	Specific matrix	Fortification range (ppm)	Range of Recoveries (%)	n	Mean Recovery ± SD (%)
	Method 476/0—M510F53				
	Milk	0.01	93.2, 107.5, 108.8	6	102.1 ± 7.4
		0.1	95.6, 97.6, 109.9		
	Liver	0.05	80.8, 97.5	6	93.4 ± 10.8
		0.5	89.2, 106.0		

Appendix IV Environmental assessment

Table 1 Water model inputs for drinking water assessment of BAS 510F

Parameter	Turf	Crops
Maximum single application rate (g a.i/ha)	400	330
Maximum number of applications	6	6
Minimum interval between applications	14	7
Method of application	field sprayer	field sprayer
Molecular weight	343.2 g/mol	
Solubility in water at pH 7	4.64 mg/L	
Vapour pressure	$<1.33 \times 10^{-7}$ kPa at 25°C	
Henry's Law constant	5.11×10^{-10} atm·m^3·mol^{-1}	
K_{ow}	915	
Hydrolysis half-life	stable at pH 5, pH 7, pH 9	
Photolysis half-life in soil	stable	
Photolysis half-life in water	stable	
Aerobic soil biotransformation DT_{50}	578 days	
Aerobic aquatic biotransformation DT_{50}	stable	
Anaerobic aquatic biotransformation DT_{50}	stable	
Adsorption K_d	3.277	
Adsorption K_{oc}	655	

Table 2 Estimated concentrations of BAS 510F in wildlife food sources after a direct overspray for turf and field crop uses

Matrix	Fresh/dry weight ratios	EEC in mg a.i./kg dry weight[a]	
		Turf	Crops
Short range grass	3.3[b]	1695	1412
Leaves and leafy crops	11[b]	2957	2464
Long grass	4.4[b]	1035	862
Forage crops	5.4[b]	1555	1296
Small insects	3.8[c]	474	395
Pods with seeds	3.9[c]	100	83
Large insects	3.8[c]	81	68
Grain and seeds	3.8[c]	81	68
Fruit	7.6[c]	244	204

[a] Based on correlations reported in Hoerger and Kenaga (1972) and Kenaga (1973) and modified according to Fletcher et al. (1994)

[b] Fresh/dry weight ratios from Harris (1975)

[c] Fresh/dry weight ratios from Spector (1956)

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